

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
 - TEXT CUT OFF AT TOP, BOTTOM OR SIDES
 - FADED TEXT
 - ILLEGIBLE TEXT
 - SKEWED/SLANTED IMAGES
 - COLORED PHOTOS
 - BLACK OR VERY BLACK AND WHITE DARK PHOTOS
 - GRAY SCALE DOCUMENTS
-

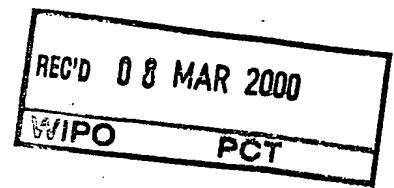
IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.

This Page Blank (uspto)



STATE OF ISRAEL



4

זאת לתעודה כי

רצופים בזאת העתקים

נכונים של המסמכים

שהופקדו לתחילת

עם הבקשה לפטנט

לפי הפרטים הרשומים

בעמוד הראשון של

הנספח.

This is to certify that
 annexed hereto is a true
 copy of the documents as
 originally deposited with
 the patent application
 particulars of which are
 specified on the first page
 of the annex.

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

This 30 -01- 2000

היום

מונוחת כל זכויות יוצרים

רשות הפטנטים
Registrar of Patents

נחתasar
Certified

לשימוש הלשכה

For Office Use

128261	מספר: Number
27-01-1999	תאריך: Date
הקודם/נדרת Ante/Post-dated	

PATENTS LAW, 5727-1967

בקשה לפטנט

Application for Patent

110/00625

אני, (שם המבקש, מענו – ולגבי גוף מאוגר – מקום התאגדותה)
I (Name and address of applicant, and, in case of body corporate-place of incorporation)

Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot Street
Herzlia 46728

דיסקוטק טכנולוגיות רפואיות בע"מ
רחוב הסדרניות 3
הרצליה 46728

LAW

הדיין

בעל אמצעאה מכח
Owner, by virtue ofשם מהו
of an invention, the title of which is

אלמנט מתרחב

(בעברית)
(Hebrew)

EXPANDABLE ELEMENT

(באנגלית)
(English)בקש בזאת כי ינתן לי עליה פטנט
hereby apply for a patent to be granted to me in respect thereof.

בקשת חלוקה – Application of Division		בקשת פטנט נוסף – Application for Patent Addition		דרישה דין קריימה Priority Claim		
מבקש פטנט from Application	No.	בקשה לפטנט to Patent/Appn.	No.	מספר/סימן Number/Mark	תאריך Date	מדינת האגוד Convention Country
מס' _____ dated _____	מס' _____ dated _____	מס' _____ dated _____	מס' _____ dated _____			
* ניפוי כח: הכל/מיוחד – רצוף זהה / עד יוגש P.O.A.: general / individual – attached to be filed later						
הוגש בעניין _____						
המען למסירת הודעה ומסמכים בישראל Address for Service in Israel						
בגטראיזשוויל עורכי פטנטים בע"מ ת"ם בול 16 פטנטים ת.ד. 10256 פינט. 2 90004						
חותמת המבקש Signature of Applicant		היום _____ בchorosh _____ שנת _____ of the year				
 עורך פטנטים בע"מ 110/00625		לשימוש הלשכה For Office Use				
בסוף זו, כשהוא מושבע בחותם לפטנטים ומושלים ומספר ותאריך ההגשתה, הינו אישור להגשת הבקשה שפורסמה רשומות לעיל.						

אלמנט מתרחב

Expandable Element

דיסקוטק טכנולוגיות רפואיות בע"מ

Disco-O-Tech Medical Technologies, Ltd.
c:110/00625

EXPANDABLE ELEMENT
RELATED APPLICATIONS

This application is a continuation-in-part of PCT application PCT/IB98/00523, which designates the U.S. the disclosure of which is incorporated herein by reference.

5

FIELD OF THE INVENTION

The present invention relates to expandable implants, especially for use as a spinal prosthesis.

BACKGROUND OF THE INVENTION

A common medical situation is that of a ruptured spinal disc. Material that exits the disc may press against the spinal cord, causing severe pain. A ruptured disc is typically treated by a surgical procedure, in which the damaged disc is partially or completely removed, and spinal fusion, in which at least the two vertebrae adjacent the removed disc are fused. Several approaches exist for spinal fusion. In one approach, the two vertebrae are connected using a plate and/or screws. In another approach, a spacer is inserted between the two vertebrae. 10 Typically, the axis of the spacer is perpendicular to the axis of the spine and to the plane of the body. Sometimes the spacer includes a plurality of holes, to encourage bone growth into the spacer. PCT publication WO 98/38918, the disclosure of which is incorporated herein by reference, describes a spacer that is inserted in a collapsed condition and expanded to fill the inter-vertebral space. Another type of spacer, exemplified by U.S. Patent 5,123,926 (and others) to Pisharodi, the disclosure of which is incorporated herein by reference, functions like 15 a concrete anchoring screw, in that a portion of the spacer, usually a center portion thereof, expands by a relatively small amount to engage the adjacent vertebrae.

U.S. Patent 5,800,549, the disclosure of which is incorporated herein by reference, describes an insertable flexible disc replacement that is inserted using a syringe. However, this 20 replacement does not fuse adjacent vertebrae, rather, it is designed to replace the form and function of a removed inter-vertebral disc.

One disadvantage of some of known fusion devices is that a relatively large entry hole in the body is required to insert the device. In some, a regular-sized surgical incision is required. In others, a minimally invasive laproscope-size hole is required.

30

SUMMARY OF THE INVENTION

An object of some preferred embodiments of the present invention is to provide an intra-vertebral spacer that can be inserted using a narrow diameter needle.

An aspect of some preferred embodiments of the invention is that a spacer having a first diameter is inserted and is then expanded to a second, much larger diameter. Preferably,

the second diameter is greater than the first diameter by a factor of three, four, five or more. Thus, a spacer for an inter-vertebral space of a 12 mm may be inserted using a needle having a 4 mm (inner) diameter. However, in some embodiments of the invention, a more modest diameter increase is achieved, for example, between 20% and 200% or 300%.

5 An aspect of some preferred embodiments of the invention relates to a family of geometrical structures useful for an expanding spacer. In a preferred embodiment of the invention, the spacer initially comprises a structure having a narrow diameter. When the spacer is expanded, the diameter increases. In a preferred embodiment of the invention, the diameter of the spacer increases at the expense of the length of the spacer, which is shortened. In a
10 preferred embodiment of the invention, the spacer is modified by the expansion from a long, substantially straight object into a shorter object have a wave-like profile. The effective diameter of the modified spacer is that of the wave, which is significantly greater than the initial diameter.

In a preferred embodiment of the invention, the spacer is formed of a hollow tube
15 having a plurality of axial slits formed on its surface. Preferably, the slits are arranged in pairs of parallel slits, each pair defining a spike, which spike is preferably formed when the material between the slits is folded perpendicular to the slits. When the tube is compressed, the spikes fold out, preferably in the shape of an inverted "V". Typically, though not in all embodiments of the invention, a spike comprises a short base, one or more (usually at least two) legs or sides
20 and optionally a top which connects the ends of the legs. In some embodiments, for example the inverted "V", the spike defines a peak vertex in stead of or in addition to the top.

In a preferred embodiment of the invention, a plurality of spikes are defined around the circumference of the tube, so that the tube "expands" in all directions. Preferably, all the spikes have the same length. Alternatively, the length of the spike may depend on an angular position
25 of the spike on the circumference. In one example, the circumference includes eight spikes per axial-length unit of tube, the cross-section of the expanded tube having a shape of a square, with four equal-length spikes at the center of each side of the square and four, longer spikes, at the four corners of the square. In a preferred embodiment of the invention, the spacer comprises a plurality of consecutive tube segments, each segment including one or more
30 spikes. In one example, a square cross-section is achieved by alternating segments of two types, one having shorter spikes (at square sides) and the other having longer spikes (at square corners). Alternatively, the spike lengths are not rotationally symmetric. Alternatively or additionally, the cross-section is not rotationally symmetric. Alternatively or additionally, the spike lengths vary as a function of the axial position and possibly also the angular position of

the spike along the spacer. In a preferred embodiment of the invention, the spike arrangement and/or length conforms to an expected shape of the inter-vertebral space.

In a preferred embodiment of the invention, each spike is defined by two parallel slits of equal length. Alternatively, the two slits are not of equal length. Alternatively or 5 additionally, the slits are not parallel, for example the slits being staggered. Alternatively or additionally, at least some of the spikes may be defined by more than two slits, for example three or four slits.

In a preferred embodiment of the invention, the slits are parallel to the axis of the tube. Alternatively, at least some of the slits or pairs of slits are not parallel to the tube. In one 10 embodiment of the invention, the slits define a spiral on the tube.

In a preferred embodiment of the invention, the extended spikes are substantially normal to the tube axis. Alternatively, at least some of the spikes are at an angle to the axis. In one example, the outside spikes are angled out, for example to better grasp surrounding bone tissue. In another example, at least some of the spikes are angled in, for example to exert 15 compressive forces on a bone, for example to bring together a broken bone into which the spacer is inserted.

In a preferred embodiment of the invention, the spikes are substantially straight. Alternatively, at least some of the spikes are curved, for example in a plane which includes the spike and the tube axis and/or out of the plane. Alternatively to being curved, at least one spike 20 may comprise a plurality of straight portions, each portion at an angle to another portion of the spike.

In a preferred embodiment of the invention, the spikes are normal to the tube surface. Alternatively, at least one of the spikes is not normal to the surface. In one example, the spikes exit the tube surface at a parallel or near-parallel angle to the tube surface.

25 In a preferred embodiment of the invention, the expanded spacer defines a generally cylindrical shape, whose axis is coincident with the axis of the tube. In some embodiments, the cross-section of the expanded spacer is other than a circle, (e.g., a rectangle), but such a spacer preferably has a main axis which is coincident with that of the tube. In other preferred embodiments of the invention, however, the main axis of the expanded spacer is not coincident 30 with that of the tube. In one example, the axes may be parallel, for example if when viewing the spacer cross-section all the spikes on one side of the spacer are longer than those on an opposite side. In another example, the axes may be non-parallel or even non-planar: One situation where non-parallel axes are useful is when the spacer is inserted between the vertebra at an oblique angle (e.g., from a posterior-lateral direction). In such an insertion, it is still

desirable that the expanded spacer be parallel to the vertebral end-plates. In a preferred embodiment of the invention, the spike lengths on the spacer are arranged so that when a spacer is inserted at the oblique angle and then expanded, the axis of the expanded spacer profile is substantially aligned with one of the axes of the body. In some cases, two spacers are inserted at different oblique angles, so that they better fill the intra-vertebral space.

In a preferred embodiment of the invention, the cross-section of the tube is circular. Alternatively, the cross-section is that of a polygon, for example a square or a triangle, preferably one having a same number of sides as there are spikes around the circumference of the tube.

10 ~~Alternatively to spikes being formed of a surface of a hollow tube, the tube itself~~
(which need not be hollow), or a ribbon, may distort to form a wavy side profile.

An aspect of some preferred embodiments of the invention relates to forming the tube of a material having an uneven thickness and/or mechanical strength. In a preferred embodiment of the invention, increased thickness and/or strength is provided at points where 15 stress is concentrated when pressure is applied to the spikes in an expanded spacer. Alternatively or additionally, increased thickness and/or strength is provided at points where stress is concentrated when pressure is applied to the spikes in an expanded spacer. Alternatively or additionally, increased thickness and/or protrusion is provided on one or more spikes to mechanically block a collapsing of the spikes after the tube is expanded. In one 20 example, when the spacer comprises alternating segments of spikes, a segment may include one or more protrusions which strengthen the spikes on an adjacent segment. Alternatively or additionally, a lower strength and/or pre-stressing is applied to portions of the tube which are expected to fold when the tube is expanded. Alternatively or additionally, variations in thickness and/or strength and/or elasticity define portions of the spacer which better conform 25 to surrounding tissue.

An aspect of some preferred embodiments of the invention relates to spikes having a non-V shaped profile. In a preferred embodiment of the invention, the spikes have a flat top, possibly with small protrusions formed thereon, so that the spikes do not dig into the vertebrae. Alternatively or additionally, the spikes have concave sides, so that when are 30 stressed, they do not collapse.

An aspect of some preferred embodiments of the invention relates to the expansion of a spacer. In a preferred embodiment of the invention, the expansion proceeds from one end of the spacer to the other end, with spikes at one segment of the spacer being fully extended before adjacent spikes are extended. Alternatively, all the spikes are extended at the same time.

Alternatively, the order of extension is not controlled. Alternatively, at a first group of spikes are partially extended, then, after other spikes are at least partially extended, the first group of spikes are extended to a greater amount. In a preferred embodiment of the invention, the expansion of the spacer is controlled by a shaping element inserted therein and/or using an outer collar which limits the extension of the spikes. Possibly, the spacer includes an inner thread to engage the shaping element. Alternatively or additionally, the expansion is controlled by providing different parts of the spacer with different mechanical strengths, so that when expanded, the weaker parts expand first.

An aspect of some preferred embodiments of the invention relates to limiting an extension dimension of the spikes. Generally, a spike is defined by two sides of a folded strip of material, which, together with a base defined by section of the tube (or of its axis), form a triangle (or other shapes, as described below). Since the length of the two material sides of the spike are generally limited by the slits to a fixed amount, the final extended length of the spike (i.e., the triangle height) is inversely related to the length of the base. In some embodiments of the invention, the spacer is axially compressed so that the length of the base is substantially zero (excluding the thickness of the spike itself). Alternatively, in a preferred embodiment of the invention, an axial contraction of the tube is restricted, so that the length of the base is significant. Preferably, a protrusion in the spike, in one or both of the two sides of the spike, defines a minimal distance between the sides, and hence a minimum size base and a maximum length of a spike. Alternatively, the tube body itself may include a mechanical limitation to its contraction. In one example, two slits may define a section of material which, when the tube is expanded (and axially compressed) folds upon itself or protrudes inside the tube, rather than extending outward as a spike. The axial contraction is thus limited by the thickness of the folded material or by the material butting against the inside of the tube.

Alternatively to a spike being defined by two legs, a spike may be defined by three or more legs which are non-planar. In one example the three legs and the base form a spike having a tetrahedral shape. Alternatively, two legs and a top (rather than a base) may be used to define a spike having a rectangular or an upside-down triangle profile.

An aspect of some preferred embodiments of the invention relates to sections cut out of the tube. In a preferred embodiment of the invention, the missing sections are used to define an expanded spacer geometry. In one example, a section of the tube which defines a spike is mostly missing from the spacer. When the spacer is expanded (and axially compressed) the two sides of the missing section advance until they abut and further axial contraction is impossible or meets a greater resistance. In another example, a missing section of the tube

makes one side of the spacer weaker and causes the spacer to bend in that direction when expanded.

Alternatively or additionally, missing sections of the spacer (tube and/or spike portions) may exist for encouraging bone growth into the spacer.

5 Alternatively or additionally to missing sections of the spacer, one or more slits may be defined in the spacer to affect its expanded geometry, possibly independently of the spike geometry.

An aspect of some preferred embodiments of the invention relates to spacers which include struts, where each strut preferably interconnects two or more spikes, when the spacer is 10 expanded. In a preferred embodiment of the invention, the struts are formed from the surface of the tube which also forms the spikes. Alternatively, the struts are provided by a second layer of material overlaid and/or under-laid on the layer from which the spikes are formed. The second layer is preferably attached to the first layer only at points where the struts are to be connected to the spikes, in the expanded spacer.

15 In a preferred embodiment of the invention, the struts inter-connect spike peaks. Alternatively or additionally, the struts may connect spike sides, for example at their centers. Alternatively or additionally, the struts may connect sides with peaks. Alternatively or additionally, the spikes may connect spike portions with the tube itself. Preferably, although not required, the interconnected spikes and struts form triangular or tetrahedral shapes.

20 In a preferred embodiment of the invention, a single strut interconnects two spikes. In some embodiments, a single spike may be connected to more than one strut, for example, in a spacer having four spikes around its circumference, four struts may be provided to form a ring which encloses the spacer cross-section. Alternatively or additionally to radially interconnecting spikes, the struts may axially inter-connect spikes, for example forming a line 25 of struts which is parallel to the axis of the spacer. Substantially any spike interconnection pattern may be provided, for example, a spiral strut path which interconnects spikes to define a spiral path on the expanded spacer.

In a preferred embodiment of the invention, the struts are parallel to the outline of the cross-section of the spacer, for example defining a rectangle if the spacer has a rectangular 30 cross-section. In other embodiments, however, such parallelism is not required. For example, the struts may define a rectangle which is rotated at 45° relative to the spacer cross-section.

In a preferred embodiment of the invention, the struts are arranged in a radial symmetry. Alternatively or additionally, the struts are arranged in an axial symmetry. Alternatively, the struts are arranged asymmetrically. Preferably, the pattern of strut-

asymmetry matches and/or is aligned with a pattern of spike asymmetry. Alternatively, the patterns do not match and/or are not aligned.

In a preferred embodiment of the invention, the struts structurally limit relative movement between spikes and/or spacer portions, preferably, by resisting movement of two points connected by spikes towards (and/or away from) each other. Alternatively or additionally, the struts may provide other structural support, for example, to limit relative outward movement of two points, to limit expansion of a portion of the spacer, to limit certain deformations of the spacer under stress and/or to limit spike extension. Alternatively or additionally, one or more of these functions may be provided by wires. As used herein the differences between wires and struts, both of which are examples of connecting elements) are mainly in their relative rigidity and thicknesses. Additionally, struts usually maintain the same rigid configuration when the spacer is expanded and when it is collapsed, wires may change their configuration, for example being folded when the spacer is collapsed and being extended when the spacer is expanded. Alternatively or additionally, to directly structural functions, the struts and/or wires may be used to effect a desired contact surface, for example, to enhance fusion with bone or to limit embedding to spikes in the surrounding bone.

In a preferred embodiment of the invention, the connecting elements have a fixed cross-section. Alternatively, the cross-section and/or the mechanical properties may vary along the length, width and/or thickness of a connecting element. Possibly, different connecting elements (e.g., different struts) may have different geometries and/or material properties.

An aspect of some preferred embodiments of the invention relates to a tissue excavation tool, especially for disc removal. In a preferred embodiment of the invention, the tool comprises an elongate member having at the end thereof an expandable portion comprising a plurality of spikes. The tool may be inserted into the spine at a small diameter and the spikes are then extended. Tissue excavation is preferably performed by rotating the tool, so the spikes disintegrate the disc tissue. Preferably, the tool is hollow so the disintegrated tissue may be vacuumed out of the intra-verbal space. Alternatively or additionally, the tool may be bent, to reach locations out of line with from the entry point of the tool. Alternatively or additionally, a stylet is inserted into a hollow of the tool, to guide it to various locations in the inter-vertebral space.

An aspect of some preferred embodiments of the invention relates to using an expandable structure for other uses, for example for bone anchoring, for tooth implanting, for supporting fractured bones and/or for gradually modifying bone structure. In a preferred embodiment of the invention, the spacer is inserted into a bone to be modified and/or

supported using a needle. In one example, the spacer is inserted in an unexpanded position and once the bone segments are aligned, for example using x-ray imaging techniques, the spacer is expanded to grasp the bone segments and possibly urge them together. In a preferred embodiment of the invention, the spacer may be removed once the bone is knit by collapsing the spacer and removing it using a thin cannula.

An aspect of some preferred embodiments of the invention relates to controlling the configuration of an implanted spacer using externally applied power and/or controls. In a preferred embodiment of the invention, the expansion of the spacer is increased and/or decreased responsive to such externally applied power and/or controls signals. Preferably, such increase and/or decrease is used to gradually bend, straighten, lengthen and/or shorten bones in which the spacer is implanted, for example ribs or leg bones. In one example, bones are bent and/or straightened, using a spacer whose bend is related to its axial length. Preferably, a spacer for bone modeling automatically extends/distorts by a predetermined amount each day and/or in response to an outside command.

An aspect of some preferred embodiments of the invention relates to using the implanted spacer to report on internal physiological parameters. In one example, the spacer reports a degree of bone ingrowth, such as to enable a treating physician to monitor the healing process. In another example the spacer reports applied torque and pressure, such as to enable a treating physician to assess structural problems of the bone and/or the spacer. In a preferred embodiment of the invention, a sensor, for example a silicon pressure or strain sensor) is integrated with the spacer. Alternatively, the body of the spacer itself provided at least some of the sensing, for example, by vibrational modes of the spacer changing responsive to bone ingrowth and/or by tracking (using medical imaging techniques) changes in the configuration of the device and especially configuration changes in designated pressure sensitive portions thereof.

There is therefore provided in accordance with a preferred embodiment of the invention, an expandable spacer, comprising:

a tube having a surface and an extent,
wherein, said surface defines a plurality of slits, said plurality of slits defining a second plurality of spikes, such that when said tube is axially compressed, said spikes fold out of said surface.

There is also provided in accordance with a preferred embodiment of the invention, an expandable spacer comprising a tube having an extent and a diameter and defining a plurality of slits thereon, wherein, said spacer is designed to have two configurations, a first

configuration in which said extent is long and said diameter is small and a second configuration in which said extent is shorter and said diameter is larger.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more clearly understood from the following detailed description of the preferred embodiments of the invention and from the attached drawings, in which:

Fig. 1A shows a flat projection of an expandable spacer, in an un-expanded configuration thereof, in accordance with a preferred embodiment of the invention;

Fig. 1B shows a perspective view of the spacer of Fig. 1A;

Fig. 1C shows both an axial flat projection and a front flat projection of the spacer of Fig. 1A, in an expanded configuration thereof;

Fig. 1D shows a perspective view of the spacer of Fig. 1A, in an expanded configuration thereof;

Figs. 2A-2D illustrate a process of inserting and expanding a spacer, in accordance with a preferred embodiment of the invention;

Figs. 2E-2G illustrate methods of controlling an expansion of a spacer, in accordance with preferred embodiments of the invention;

Figs. 2H-2J illustrate removable and/or adjustable spacers, in accordance with preferred embodiments of the invention;

Figs. 2K-2L illustrate shaped tips for controlling the expansion of a spacer, in accordance with a preferred embodiment of the invention;

Fig. 2M is a spread layout of a spacer including an expansion limiting wire, in accordance with a preferred embodiment of the invention;

Fig. 2N is a spread layout of a self-bending spacer, in accordance with a preferred embodiment of the invention;

Fig. 2O illustrates a spacer having an internal end-cap, in accordance with a preferred embodiment of the invention;

Fig. 2P illustrates a spacer having a collapsed axis which is not parallel to an expanded axis of the spacer, in accordance with a preferred embodiment of the invention;

Figs. 3A-3E are axial views of spacers with struts in accordance with preferred embodiments of the invention;

Figs. 3F-3M illustrate one method of providing struts between spikes, in this example struts which ring the spacer at the spike peaks;

Fig. 4A shows a flat projection of a spacer having a square profile when expanded, in an un-expanded configuration, in accordance with a preferred embodiment of the invention;

Fig. 4B shows both an axial flat projection and a front flat projection of the spacer of Fig. 4A, in an expanded configuration thereof;

5 Fig. 4C is a perspective view of the spacer of Fig. 4A, in an expanded configuration;

Fig. 4D illustrates a spacer configuration in which one spacer is expanded within another spacer;

Fig. 5 illustrates a spacer in which slits are formed on the spacer in a spiral pattern;

10 Figs. 6A-6V illustrate variants of spikes and/or spike orientations, in accordance with alternative preferred embodiments of the invention;

Figs. 6W and 6X illustrate spikes having portions which twist when the spacer is expanded;

Figs. 6XA-6XC illustrate a flat-top spike in accordance with a preferred embodiment of the invention;

15 Figs. 6XD-6XH illustrate a flat-top spike in accordance with another preferred embodiment of the invention;

Figs. 6XI-6XL illustrate a method of removing portions of a spacer, to achieve a desired spike shape;

20 Fig. 7 illustrates protrusions on a spacer portion, in accordance with a preferred embodiment of the invention;

Figs. 8A-8B illustrates spacers for which axial shrinkage of the spacer is limited by the design of a tube portion of the spacer, in accordance with preferred embodiments of the invention;

25 Fig. 9A illustrates an excavating tool, in accordance with a preferred embodiment of the invention;

Fig. 9B illustrates the tool of Fig. 9A, in a bent configuration, in accordance with a preferred embodiment of the invention;

Figs. 10A-10C illustrate an expandable bone implant, in accordance with a preferred embodiment of the invention;

30 Fig. 11 is an exploded view of a dental implant device in accordance with a preferred embodiment of the invention; and

Figs. 12A-12C illustrate the use of an axially contracting tissue fastener, in accordance with a preferred embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1A shows a flat projection of an expandable spacer 20, in an un-expanded configuration thereof, in accordance with a preferred embodiment of the invention. Fig. 1B is a perspective view of spacer 20. Spacer 20 comprises an elongate hollow object 22, such as a tube, having a plurality of spikes 24 defined thereon (in a flattened form), each spike being defined by a pair of slots 26. In a preferred embodiment of the invention, the cross-section of tube 22 is a circle, as shown in an axial projection 36 of the spacer. In the embodiment shown in Fig. 1A, tube 22 includes alternating spike segments 28 and non-spoke segments 30. At one end of the tube, an end-cap 34 is preferably defined. In a preferred embodiment of the invention, end-cap 34 is hollow. Alternatively, end-cap 34 is solid, but preferably comprising a porous material or including holes, to enhance bone ingrowth. Alternatively or additionally to end-cap 34, spacer 20 is attached to the end of a tube, such that only a portion of the tube, preferably an end portion, has slits defined therein.

Figs. 1C-1D show spacer 20 in an expanded configuration, Fig. 1C using a flat projection (side and axial) and Fig. 1D using a perspective view. When expanded, spikes 28 extend outwards and tube 22 is axially compressed. Non-spoke segments 30 and end-cap(s) 34 preferably do not distort. As can be seen in the figures, a considerable expansion in diameter is achieved, for example a five fold expansion. In addition, a considerable axial contraction is achieved, as evidenced by comparing the thickness of a spike 24 in Fig. 1C (38) with Fig. 1A (28).

Although spacer 20 has been described as including non-spoke portions, it should be appreciated that in some preferred embodiments of the invention no such non-spoke portions are defined, for example, if the slits are interleaved, as shown by the example of a dotted line 35 in Fig. 1A.

In a preferred embodiment of the invention, tube slits 26 include round holes, for example holes 32, at their ends. Preferably, these holes are defined to reduce the propagation of stress and/or mechanical failure in tube 22. Alternatively or additionally, these holes are defined to weaken the end of the slit so that when spacer 20 is axially collapsed, spikes 28 will preferentially fold out at the ends of the slits. Alternatively or additionally, slits 26 may include holes 33 at their center (the apex of spikes 28), to encourage folding of the spike at the location of the hole.

The above is a description of a limited subset of spacers, further variations are defined below.

Figs. 2A-D illustrate a process of inserting and expanding spacer 20. In Fig. 2A, a damaged disc 54 is located in an inter-vertebral space 55, between a vertebra 50 and a vertebra

52. Typically, before inserting a spacer between the two vertebra, disc 54 is partially or completely removed. Preferably, disc 54 is removed using a minimally invasive technique, preferably using only a thin needle 56, for example as described below with reference to Fig. 9A and 9B. Alternatively, a laproscopic approach is used, for example as described in WO 98/38918, preferably taking care to minimize trauma to the patient.

In Fig. 2B, the disc has been removed and a spacer 20 is inserted into inter-vertebral space 55, in an un-expanded configuration. In a preferred embodiment of the invention, spacer 20 is mounted on- or formed at- the end of an elongate member 60. Preferably, spacer 20 is inserted using a syringe or in an "over-tube" which may be retrieved, once the spacer is inserted. ~~Alternatively or additionally, spacer 20 is inserted using X-Ray guidance, to avoid damaging the spinal cord.~~

In Fig. 2C, spacer 20 is in the process of being radially expanded (and axially shortened). A portion 62 of spacer 20 is expanded, while a portion 64 of spacer 62 is not yet expanded.

15 In Fig. 2D, spacer 20 is expanded over its entire length and it fills inter-vertebral space 55. In a preferred embodiment of the invention, a fixing material, such as a bone slurry or a setting fixing compound is provided into inter-vertebral space 55, in order to encourage fusion between vertebra 50 and vertebra 52. In the case of a bone slurry, bone chips or bone powder, such setting may require a week or so of bed rest. Preferably, spacer 20 is stiff enough to 20 maintain its shape until the bone sets, so that little or no bed rest is required. Alternatively or additionally, at least some of the required stiffness is provided by the fixing material. Alternatively or additionally, to injecting a fixing material or as part of the fixing material, growth hormones, enzymes, anti-bacterial pharmaceuticals, anti-inflammatory compounds and/or other bio-active materials may be injected into space 55, to encourage fusion and/or 25 another desired effect.

In a preferred embodiment of the invention, the fixing material is provided through member 60. Alternatively, it is provided using a syringe. It will be appreciated from viewing Fig. 1D that in the expanded configuration, spacer 20 can include ample holes for a bone slurry (and/or new bone growth) to flow between inter-vertebral space 55 and the inside of spacer 20. 30 In a preferred embodiment of the invention, spacer 20 is coated with a bone-growth enhancing material, such as a hormone. Alternatively or additionally, spacer 20 is coated with a material to which new bone growth adheres. Alternatively or additionally, spacer 20 has a rough finish, at least on portions thereof, to encourage bone adhesion thereto. In one example, the finish is created by sandblasting at least portions of the spacer. Alternatively or additionally, the spacer

may have holes and/or small protrusions formed thereon, to encourage bone ingrowth. Such holes may be formed on the tube portion and/or on the spikes. Preferably, areas surrounding such holes are treated to be stronger, so that the existence of the holes does not adversely affect the expansion geometry of the spacer.

5 Alternatively, at least some parts of spacer 20 may be treated to retard bone growth, for example by making them radioactive or by coating them with bone-growth retarding material. Such retardation may be useful in order to allow removal of the spacer (described below). Preferably such retardation is short-term, and the effect fades after a time, so that if the spacer is not removed, bone growth will surround it. Alternatively or additionally, at least a part of

10 the spacer has a finish and/or a geometry (e.g., no holes) which discourages bone ingrowth. Additionally or alternatively, the spacer may enclose or be enclosed in an impenetrable material, for example a balloon, which is inflated by the spacer being expanded. Possibly, the balloon surface is conducive to tissue attachment and/or degrades after a time. Alternatively, the balloon is attached to the spacer along its length and the spacer is expanded by inflating the
15 balloon.

The next step in the implantation method is preferably to close up the incision used to provide spacer 20, or, more typically, in a minimally-invasive procedure, to retract member 60. In some preferred embodiments of the invention, the bone slurry may be injected with a needle after member 60 is removed, rather than while member 60 is still inserted.

20 In a preferred embodiment of the invention, spacer 20 is attached to member 60, for example by a threaded coupler, so at the end of the procedure member 20 is disengaged from spacer 60.

Alternatively, spacer 20 forms an extension of member 60. In a preferred embodiment of the invention, spacer 20 is cut off at or near the point where it enters inter-vertebral space
25 55, for example using a cutting tool which is inserted inside or over member 60. Alternatively, member 60 is twisted off spacer 20. Preferably, a member 60 is weakened at its connection with spacer 20. It is noted that the un-expanded spacer portions are relatively weak compared to the expanded portions (which may be firmly engaged by bone). Thus, an un-expanded portion of spacer 20 may serve as the weakened connection point. Possibly, member 60 is
30 twisted off spacer 20 (and then any resulting sharp edges may be smoothed off, possibly using a tool inserted through or over member 60). Alternatively or additionally, spacer 20 includes a sleeve which overlaps the weakened connection point. Thus, when member 60 is twisted off, any jagged edges remain covered by the sleeve and do not come into contact with the tissue surrounding the spacer. Alternatively or additionally, after the expansion of the spacer is

completed, the jagged [redacted] is capped. The cap may be threaded on the end of the spacer. Alternatively or additionally, the cap has the form of a bolt having an end-cap attached to an elongate threaded portion. The elongated threaded portion engages the spacer, possibly at its far end and the end-cap pushes against or engages (possibly using a thread) the near end of the spacer.

One consideration in spacer implantation is ensuring spacer 20 fits inter-vertebral space 55. In a preferred embodiment of the invention, a plurality of spacers are available for implantation (for example in a kit), each with a different (compressed) axial length and/or different radial diameter. The required spacer size may be determined from measurements on a

10 CT image or an x-ray image of inter-vertebral space 55.

Alternatively or additionally, once the spacer is expanded as shown in Fig. 2D, any extraneous spacer portion (i.e., protruding out of inter-vertebral space 55) is cut off. The removed spacer portion may be expanded, partially expanded or non-expanded. In a preferred embodiment of the invention, the cut is made from inside member 20, for example using a

15 rotating cutting edge which is mounted on a narrow elongate member which is inserted inside member 60.

In a preferred embodiment of the invention, the surgical approach is from the back of the patient. Alternatively, a lateral approach may be used. It is noted that the implanted device may be very narrow during implantation, so it is easier to plan an approach. Alternatively or

20 additionally, it is noted that the spacer, in some preferred embodiments of the invention, may be made flexible along its main axis, at least in its un-expanded configuration. Thus, it can be provided at inter-vertebral space 55 using a curved guide, possibly a flexible guide, such as an endoscope or a catheter. Fig. 2P, below, describes an alternative method of insertion.

Figs. 2E-2G illustrate various methods of effecting and/or controlling the expansion of a spacer, in accordance with preferred embodiments of the invention. In Fig. 2E, the expansion is essentially uncontrolled. A spacer 70 is expanded using an expansion member 72 attached to its end-cap 74. When member 72 is moved in the direction of the arrow relative to spacer 70, the resulting stress axially collapses spacer 70, causing the spikes to expand out. The order of expansion of the spikes is dependent, inter alia, on the relative stiffness of the spikes. Usually all the spikes will be about the same stiffness, so the expansion may be gradual over the whole spacer or sudden at points which fail first. Alternatively, the spacer may be constructed so that some spikes are weaker, by design, than other spikes, so that a certain order of spike extension can be defined.

In a preferred embodiment of the invention, the relative movement of member 72 comprises maintaining member 72 in location relative to the vertebrae and pushing spacer 70 towards the end of member 72. Preferably, the relative motion is achieved by direct application of force. Alternatively, the relative motion is achieved using a screw action, which can be more gradual and controllable. Threading of the spacer may be anywhere along member 60. However, in some preferred embodiments of the invention, spacer 70 is provided with an inner thread at the end of the spacer opposite from end-cap 74.

In a preferred embodiment of the invention, member 72 is removed from spacer 70 at the end of the expansion process by applying a sudden impulse force to break the connection between the member and end-cap 74. Alternatively, member 72 is twisted off end-cap 74.

Alternatively, especially if the relative motion is achieved using a threading of spacer 20, member 72 is coupled to end-cap 74 using a thread which is preferably counter to the threading of the spacer. Thus, member 72 can be screwed off. In some embodiments the end-cap threading is in the same direction as the threading of the spacer.

Fig. 2F illustrates a spacer 80 which is expanded using an internal spacing member 82. However, unlike the example of Fig. 2E, the expansion is controlled, using a collar 84 which does not allow spikes to extend from spacer 80, except at designated areas. Preferably, the designated areas are at the end of collar 84. Alternatively, especially as shown with reference to Fig. 2G, the designated areas may be in the middle of the collar. Alternatively or additionally to an external collar 84, spacer 80 may also utilize an internal collar. Preferably, the internal collar engages spacer 80 using an external thread on the collar and/or an internal threading on spacer 80. Alternatively or additionally, no threading is used. possibly, the spacer is expanded by direct pulling and not by a screw-action.

In a preferred embodiment of the invention, movements of an internal collar and an external collar are synchronized to control the expansion of the spacer. In one example, the spacer is advanced out of the external collar by rotating the external collar relative to the spacer (there is preferably a threaded coupling between them). Thus, the newly "extruded" portion of the spacer is unexpanded and unconstrained. Thereafter or possibly synchronously therewith, the internal collar or a member 72 is retracted, again possibly by rotating it relative to the spacer (preferably utilizing a threaded coupling therebetween), causing axial strain on the spacer, which expands the newly extruded portion. In some embodiments, the internal and external collars may be rotated simultaneously, but each of the collars has a different thread angle relative to the spacer, so each translates a same rotational movement into different axial movements.

In some embodiments, member 72 and/or an internal collar are maintained at a desired angle relative to the spacer using a groove in the member which matches one or more rails and/or a series of protrusions on the inside of the spacer. In some embodiments, the rail, groove and/or protrusions are not arranged in a straight line.

5

Skipping ahead, Figs. 2K and 2L illustrate shaped tips for a collar 84, in accordance with a preferred embodiment of the invention. One effect of the shaping is a preferential expansion of one or more spikes (which are unconstrained by the collar) relative to other spikes which are constrained, thereby allowing control of the expansion of the spacer and/or extension of the spikes.

10

Returning back, Fig. 2G illustrates a spacer 90 whose expansion is controlled using an external framework 92. In a preferred embodiment of the invention, framework 92 includes a plurality of holes 94. When spacer 90 is moved relative to framework 92, spikes can only extend through pre-designated holes 94. The relative motion of the spacer may be achieved using any of the techniques described above. It is noted however that since spacer 90 is pushed against framework 92, there is no requirement for an internal member, in some preferred embodiments of the invention. In some preferred embodiments of the invention framework 92 is left in the body. In a preferred embodiment of the invention, at least some of holes 94, have the form of axial or transverse slots, through which spikes may extend. Thus, in some embodiments, framework 92 comprises tines connected to a collar, the tines defining the above slots, which are open in the direction of the spacer. Such a framework may be retracted after the spacer is expanded.

15

20

In a preferred embodiment of the invention, such a framework may be used to control the distortion of a solid member, for example a wire, in which the "expansion" is achieved by a straight element folding into a wavy ribbon shaped element (each spike being a bend in the ribbon). Preferably, a plurality of weakened points, strengthened points and/or areas of increased cross-section are formed along the wire, to limit and/or otherwise control the extent of the wire which is pushed out through holes in framework 92.

25

Alternatively or additionally, the expansion of the spacer may utilize a balloon (not shown) which is inserted in the lumen of the spacer and, when expanded, radially extends the spikes. Generally, the "ring" segments of the spacer are not affected by the balloon.

Alternatively or additionally, the ring segments may also be deformed by the balloon. In one example, the ring segments comprises a mesh material, which can expand, but not as much as the spikes. In a preferred embodiment of the invention, the ring segments plastically deform at

a greater applied force level than the spikes, so that the spikes extend out before the rings are deformed.

In some cases, it may be necessary to adjust the length of the spikes after the spacer is inserted, possibly even a few days after the spacer insertion procedure is completed. Also, if 5 the spacer is incorrectly implanted, for example, as evidenced by x-ray images, it may be necessary to remove the spacer. In accordance with preferred embodiments of the invention, the spacer can be adjusted and/or removed.

In a preferred embodiment of the invention, removing the spacer comprises un-expanding the spacer so that it has a narrow diameter and then removing the spacer. Typically, 10 ~~the process of un-expanding the spacer extends the axial length of the spacer, so that some of~~ the spacer may be "self-removing". Preferably, an end of the spacer is restricted in motion, so that it does not move, while moving another end away from the restricted end. Alternatively or additionally, the another end of the (axially extending) spacer is guided so that it does not impact on sensitive tissues.

15 The tension of a spacer may be varied by increasing (or decreasing) the spike length, thereby pressing with a greater (or lesser) force against surrounding bone tissue. Alternatively, the tension may be increased by adding resilient material into the spacer or the inter-vertebral space, preferably using a needle. In one example, shown with reference to Fig. 4D, a second spacer (142) is inserted into a first spacer (144). Decreasing the spike length may increase the 20 length of the spacer by an unacceptable amount. Preferably, the extra length of the spacer is cut off and removed from the body.

In a preferred embodiment of the invention, one or more of the following three characteristics of the spacer should be independently controllable: spacer axial length, spike 25 length and spike tension. In some embodiments, these characteristics are controlled by selecting, for insertion, a particular spacer from a set of available spacers. In other embodiments, a spacer may be adapted to have the desired characteristics, for example, length can be controlled by not expanding the entire spacer, and cutting off the un-expanded portion. Additionally, in some embodiments of the invention, it is desirable to modify the characteristics of a spacer after it is inserted. Thus, allowing a spacer to be maintained at- or 30 modified to- an optimal operating configuration while inside the body.

In some cases, what is desired is a modification of the spacer length, with any associated change in tension or spike length being undesirable or ignored. As described above, the tension in a spacer may be increased by inserting a second spacer.

Figs. 2H-2J illustrate various methods of modifying geometrical and/or tensile characteristics of a spacer, after it is expanded. A trivial type of modification is removing the spacer and optionally inserting a new spacer or the same spacer after it is modified. In a preferred embodiment of the invention, removing a spacer includes collapsing the spacer and
5 then removing the resulting narrow-diameter tube.

Fig. 2H illustrates a spacer 100, which is further expanded or collapsed using a maintaining member 106 and a grasping member 104. In essence, member 104 engages one end of spacer 100 and member 106 engages a second end of spacer 100. When the two members are moved relative to each other, the spacer is expanded or un-expanded. In a
10 preferred embodiment of the invention, maintaining member 106 engages an end-cap 108. The engagement may be simple contact, fitting member 106 into a depression in end-cap 108 or a threaded connection. Grasping member 104 preferably grasps spacer 100 at its near end 102, preferably using an internal threaded connection on end 102. Alternatively, an external connection to end 102, possibly a threaded connection may be used. In a preferred
15 embodiment of the invention, when modifying spacer 100, member 106 is maintained in place, so that end-cap 108 does not advance into the body.

Fig. 2I illustrates a spacer 110 which is un-expanded (or completely collapsed) by the insertion of a screw or a bushing 112 into the spacer. Alternatively, the screw remains in the spacer when the spacer is inserted. Screw 112 engages a threaded end 118 and an end-cap 116.
20 When the screw is turned, the spacer is un-expanded. In a preferred embodiment of the invention, the screw is inserted using a syringe, possibly forming a needle of the syringe. Alternatively, the screw is engaged at a head 114, using an inserted screw-driver.

In a preferred embodiment of the invention, screw 112 is inserted into the spacer using a needle. In a preferred embodiment of the invention, the screw is screwed into the spacer.
25 Alternatively, the near spacer end-cap has the form of a keyhole with a larger diameter portion through which the screw can be inserted and a smaller diameter portion which the screw can engage. Optionally, instead of the far end-cap engaging the screw, it only acts as a stop against which the screw can push.

In a preferred embodiment of the invention, the inner lumen of the spacer includes a
30 threading and/or protrusions which the screw can engage. Optionally, the protrusions are created by the expansion of the spacer. Additionally or alternatively, the protrusions form a guide which guide an inserted needle of screw through the spacer to its far end-cap, resisting deviations which would make the needle/screw exit the side of the spacer. Preferably, this type of guidance is provided when the spacer has a bent configuration inside the body.

In a preferred embodiment of the invention, the near end-cap of the spacer includes a flared opening to ease the insertion of a screw, needle or screw driver head into the spacer and/or to engage the end cap. Additionally or alternatively, a guiding mechanism may be provided, for example, a magnetization of the end cap and a corresponding magnetic sensor on the inserted object or an ultrasonic transducer. Additionally or alternatively, a wire guide remains attached to the spacer after it is inserted and an endoscope or other inserted object may be guided to the spacer by following the wire. Optionally, the one end of the wire exits the body. Additionally or alternatively, the wire's end is easily identifiable, for example, by having a large radius ball attached thereto.

Fig. 2J illustrates a spacer 120 having an integral expansion control mechanism. An internally threaded tube 122 is provided in conjunction with an externally threaded screw 124. When an end-cap 126 of the screw is rotated, the screw moves relative to the tube and the spacer expands or un-expands. Alternatively, the tube may be rotated and the screw is fixed (i.e., the tube is rotatable relative to the spacer and the screw is fixed to the spacer, at least with respect to its rotation). A screwdriver 128, or at least its tip is preferably inserted until the screw. Alternatively, spacer 120 may include a ratchet mechanism, whereby a member 124 may be pushed into a holder 122, but it cannot move back out (or vice-versa). In this case, a grasper, such as grasping member 104 (Fig. 2H) is preferably provided so that motion of spacer 120 can be controlled.

In one preferred embodiment of the invention, the interior of spacer 120 provides the function of tube 122 (or of a holder 122), preferably being pre-threaded. In some embodiments, tube 122 is open at both ends or has holes defined therein, to aid in expelling any material which may have accumulated in its lumen. Alternatively or additionally, the diameter of screw 122 is small enough so that it does not fill the entire inner cross-section of tube 122.

In a preferred embodiment of the invention, screw 124 is inserted after the expansion of spacer 120 is completed, preferably as part of the insertion procedure. Alternatively, screw 126 may be inserted after the fact, for example when it is decided that adjustment may be desirable. Alternatively, screw 124 may be inserted to complete the expansion of spacer 120, during its original expansion.

In a preferred embodiment of the invention, the modification of the expansion of spacer 120 may be controlled by inserting an internal or external collar or a framework, as shown in Figs. 2F-2G. Thus, it is possible to modify the spike length for only part of the spacer (for example the middle or the ends) and/or to compensate for increased axial length of one part of

the spacer by extension of spikes at another part of the spacer. Alternatively or additionally, the threads and/or "end-caps" described with reference to Figs. 2E-2J may be located in other parts of the spacer than its ends.

In a preferred embodiment of the invention, the "minimum diameter" lumen of the spacer does not change when the spacer is expanded or collapsed. Alternatively, the lumen may decrease, for example, if portions of the tubes fold into the lumen rather than outside like spikes.

In a preferred embodiment of the invention, the spacer is expanded and collapsed using plastic deformation of the spacer material, whereby the tube is plastically deformed to form the expanded spacer. Alternatively, ~~at least one of the expansion or collapsing uses elastic properties of the material.~~ In one example, the spacer is formed so that it is partially expanded and then elastically deformed to be completely collapsed prior to insertion. Thus, when the expansion starts, some or all of the spikes protrude from the spacer and increased axial force on the spacer will only urge the spikes further out and not in. It is noted that some parts of the spacer may be designed to fold in, these parts may be elastically deformed away from their "interior position", prior to inserting the spacer. Fig. 6XI-6XL, described below illustrate weakening portions of the spacer to control the shape of the extended spike.

Alternatively or additionally, the spacer utilizes super-elastic properties of the material it is composed of. In one example, the spacer expands by itself to the expanded configuration, what is required is to limit that expansion until such expansion is desired. Such limitation may be achieved by maintaining an axial length of the spacer or by providing an external restraining tube which maintains the spacer in a collapsed configuration. Alternatively, the axial length may be maintained using an internal screw which engages the spacer over substantially its entire length. In one embodiment, as the spacer is advanced out of the restraining tube (or the screw), the unrestrained portion of the spacer expands and/or engages the surrounding bone tissue.

In another example, the spacer collapses by itself to the collapsed configuration, unless otherwise restrained, for example by a screw as described above and with reference to Figs. 2I and 2J. Additionally or alternatively, the spacer is maintained in shape using an interlock mechanism, preferably a ratchet-type mechanism. For example, in the embodiment of Fig. 8A (described below) two tabs may butt or overlap. If one tab includes a protrusion and the other tab includes a recess, when the tabs overlap, the protrusion engages the recess and a ratchet mechanism is formed. Additionally or alternatively, a dedicated ratchet mechanism may be

formed by a barbed elongated internal member of the spacer which is connected at one end to the spacer and which engages a different part of the spacer using the barbed other end.

Alternatively, or additionally, the expansion and/or collapsing may be partly super-elastic and partly plastic or elastic.

5 In a preferred embodiment of the invention, the super-elasticity is achieved by constructing the spacer of a shape-memory material, such as NiTi. Preferably, the material's state transition temperature is set to be about 30° C, so that the spacer does not naturally pass through a transition after it is already implanted.

In some preferred embodiments of the invention, the spacer is collapsed by cooling it.
10 In one embodiment, the spacer is formed of a shape-memory material which is cooled to make it pliable and then the spacer is collapsed as described above. In another embodiment, the spacer is formed of a super-elastic portion and a shape memory portion, with the (stronger) shape memory portion maintaining it in an expanded configuration and a super elastic portion applying forces to return to a collapsed configuration. Possibly, two types of shape memory material are provided, each with a different transition temperature. In a preferred embodiment
15 of the invention, when the spacer is cooled, the shape-memory portion applies a weaker force and the spacer collapses. Possibly, only a ratchet mechanism portion is formed of a shape memory material and a super elastic material, with the rest of the device being formed of a super-elastic material.

20 In a preferred embodiment of the invention, the entire spacer comprises a single type of material - plastically deformed, elastically deformed, super elastic or shape memory. Alternatively, the spacer comprises multiple layers of material, each with different properties. Alternatively or additionally, different parts of the spacer may have different mechanical properties and/or be formed of different materials. In one example, the ring segments are
25 plastic and the spikes are elastic. In another example, different spikes may have different elasticity properties. In another example, one side of the spacer may have one property and another side of the spacer may have a different property.

In some preferred embodiments of the invention, the end-cap protrudes from the spacer after it is expanded (as does end cap 108 in Fig. 2H). In some cases, the end cap may include a
30 spike to engage bone tissue. Alternatively, the end cap may be formed to be within a plane defined by the end-most spikes. In one example, this is achieved by pre-folding the end-cap into the spacer. Alternatively, the end-cap may be folded into the spacer as part of the expansion process, for example (with reference to Fig. 2E), inverting end-cap 74 by pulling on member 72. Alternatively, the end-cap may be manufactured to elastically fold into the spacer.

Alternatively, the deformation of the end spikes may fold the end-cap into the spacer. Additionally or alternatively, the end-cap may be retracted after the expansion of the spacer by pulling of a screw which engages the end-cap. Skipping ahead, Fig. 2O illustrates a spacer in which the end-cap is formed to be inside the spacer, so that the expanding spikes reach all the way to the end of the spacer.

In a preferred embodiment of the invention, the cross-section of tube 22 (Figs. 1A-1D) is circular. Alternatively, other cross-section are used, for example, polygon cross-sections, such as a triangle or a square. Preferably, the spikes are formed on sides of the polygon. Alternatively or additionally, they are formed at vertexes of the polygon. In a preferred embodiment of the invention, the inner cross section of the tube and the outer-cross-section of the tube have the same geometry and/or are aligned. Alternatively, the tube 22 comprises a radially uneven thickness of material. In one example, the inner cross-section is triangular and the outer cross-section is a square or a circle. Alternatively or additionally, the cross-sections may be asymmetric relative to the main axis of tube 22. Alternatively or additionally, the cross-section geometry of the tube may change along the axial dimension of the spacer. In a preferred embodiment of the invention, variations in the cross-section and/or tube material thickness are related to the spike positions and/or desired function. In one example, the tube diameter increases at the end-caps.

Fig. 2M illustrates a wire 121, which can be used, for example, to restrict the expansion of the spacer. In the figure, wire 121 will restrict the allowed distance between the peaks of its adjacent spikes, spike 123 and spike 125. If such wires are formed between the peaks of all the spikes in the circumference of the spacer, the maximum extension of the spike will be limited by the length of the wires. Alternatively or alternatively, the wire may only limit the angular distance between two spikes. Additionally or alternatively, such a wire may connect between a spike and a non-extending portion of the spacer. Additionally or alternatively, such a wire may be attached to a part of a spike other than its peak, for example to the middle of a spike's leg. As can be appreciated, in some preferred embodiments of the invention, the wires are not uniformly distributed over the spacer, for example being a function of axial position, radial position and/or spike geometry or distribution. Alternatively or additionally, some wires may be cut or removed by a physician prior to insertion of the spacer.

Typically, the cross-section of an expanded spacer is preferably selected to match a desired usage. In the vertebra, a disc may be replaced with two parallel spacers, one on each side of the spine. In this configuration, the cross-section of the inter-vertebral spacer approximates a rectangular box, which is thicker in the middle than at its ends. In a preferred

embodiment of the invention, the axial variation in cross-section may be provided by varying spike length or tube diameter, as described above. Alternatively or additionally, the cross-section shape of the spacer may be varied, for example to be a rectangle or a square. It is also noted that a square spacer often moves around less than a circular spacer does.

5 In a preferred embodiment of the invention, the axis of tube 22 in its collapsed and expanded configuration is substantially straight. Alternatively, the axis of the spacer may be curved or broken piece-wise while the spacer is inserted and/or after insertion is complete. Alternatively or additionally, the axis of the spacer may be curved or broken in the collapsed spacer.

10 ~~In one example, the spacer is manufactured in a bent configuration to aid its insertion.~~
During insertion the spacer is preferably straitened and/or otherwise adapted to the space into which it is inserted.

15 In another example, the spacer is inserted straight and then bent to adapt the spacer to the insertion space. In one example, a "C" shaped or horse-shoe shaped spacer replaces an entire disc with a single spacer.

20 The spacer may be pre-formed to be axially bent and then elastically or super- elastically maintained in a different configuration for insertion. Alternatively, the spacer is plastically deformed during the expansion, for example (with reference to Fig. 2E) if member 72 is a curved stylet or (with reference to Fig. 2F) using a curved collar. Alternatively, the spacer is bent after it is partially or completely expanded, for example by inserting a bendable stylet into the lumen of the spacer and then bending the stylet (from outside the body).

25 Alternatively or additionally, the spacer may be designed so that it bends when it is expanded. In one example, the spike slots are made uneven on opposing sides, so that the ring segments have a different axial dimension on opposite sides of the spacer. Fig. 2N is a layout of a spacer in which one spike "A" is shorter than a second spike "B" on the opposite side of the spacer. When the spacer is expanded, the uneven spike lengths will cause the spacer to bend.

30 In another example, the spike lengths are unequal on the two sides of the spacer, so when they push against the surrounding bone, the inner lumen is bent. Alternatively, the bending configuration is selected to create a desired contact and/or contact pressure between the spikes and the surrounding bone. Additionally or alternatively, the spike lengths and/or the slots are designed so that the spacer twists around its axis as it is expanded, for example, as shown in Fig. 5, where the spike slots are not parallel to the spacer axis.

Fig. 2P illustrates a spacer 130 having an inner axis 136 which is not parallel to an axis of the expanded spacer. In a preferred embodiment of the invention, spacer 130 is inserted into an intra-vertebral space 55 at an angle which is oblique relative to the main axes of the space, minimizing, the danger of damage to important body structures. However, when the spacer is expanded, an asymmetrical arrangement of spike lengths causes the final profile of the expanded spacer to match intra-vertebral space 55. In the example of Fig. 2P, spikes 132 decrease in length along the spacer and corresponding spikes 134 on the opposite side of the spacer increase in length. Optionally, a second spacer may be inserted, from the other side of the intra-vertebral space, along a doted line 138, indicated in the figure. In the embodiment of Fig. 2P the lengths of the spikes which are perpendicular to the plane of the figure are preferably equal. However, in other embodiments these spikes may also exhibit uneven lengths. In a preferred embodiment of the invention, elongate member 60 (Fig. 2) has a marking or a groove thereon which indicates the correct orientation of the spacer.

In a preferred embodiment of the invention, when the spacer expands and spikes extend, additional structural elements, called herein "struts", extend between two (or more) spikes or between one (or more) spike and the tubular portion of the spacer. For clarity, various strut configurations (in expanded spacers) will be described and then mechanisms for generating such strut configurations will be described.

Figs. 3A-3E are axial views of spacers with struts in accordance with preferred embodiments of the invention. Referring to Fig. 3A, a spacer 200 (when expanded) comprises a tubular portion 206 and a plurality of spikes 202 extending radially therefrom. A plurality of struts 204 connect peaks of spikes 202. In the example of Fig. 3A, the profile of the expanded spacer is rectangular, and four struts are provided, to form a rectangular profile which bounds the spikes.

A larger or smaller number of spikes may be defined for the circumference, for example, as shown in Fig. 3B, six spikes and six struts are provided.

Not all the spikes need to be completely inter-connected by struts, for example as shown in Fig. 3C, a strut 204A connects a spike 202A and a spike 202B; a strut 204B connects a spike 202C and a spike 202D; while no strut connects spikes 202A and 202C or spikes 202B and 202D.

Additionally, the pattern of interconnection of struts need not be symmetric. For example as shown in Fig. 3D, spikes (and struts) extend only to one side of the spacer. Possibly, these and/or other various in the struts are a function of the axial and/or radial position along the spacer.

Additionally, some spikes may be connected to struts and some not connected to any struts at all. For example as shown in Fig. 3E, where two spikes 210 and 212 are connected by a strut 214, while two spikes 216 and 218 are not connected to any spikes.

In Figs. 3A-3E, the struts are shown connected spikes which are at a same cross-section of the spacer. In some of the examples a complete ring (actually a polygon) is defined by the struts. Alternatively, the struts may connect spikes which are (also) axially displaced. Thus, possibly, a strut may be substantially parallel to the axis of the spacer. In an example of a strut interconnection pattern, the strut interconnection pattern may define a spiral around the spacer axis. These axial interconnections may be additional to or alternative to connection around the circumference of the spacer.

In the above Figs., struts were shown as connecting peaks of adjacent spikes. In a preferred embodiment of the invention, struts connect non-adjacent spikes. Alternatively or additionally, struts are connected, at least at one side thereof, to a non-peak portion of a spike, possibly even to a non-spike portion of the spacer, for example the tube, a wire or another strut.

In a preferred embodiment of the invention, struts are straight. Alternatively, at least one of the struts is bent. In one embodiment, the strut is pre-bent. In another, the strut is bent by the expansion process, for example by a wire or a second strut connected to the center of the strut. Preferably, weakened points are defined on the strut, to guide its bending.

Figs. 3F-3M illustrate one mechanism of providing struts between spikes, in this example struts which ring the spacer at the spike peaks. In other embodiments of the invention, struts may be provided using additional or alternative different mechanisms, for example by forming the spacer from a layered material in which the struts are defined by a layer other than that which defines the spikes. In this context it is useful to consider several types of joints and relative movements of joints movements:

- (a) joints which experience only axial translation during the expansion process, for example base joints of a spike;
- (b) joints which experience radial translation during the expansion process, for example peaks of spikes; and
- (c) joints which experience angular motion.

In addition, several types of relative motion may be experienced between pairs of joints, for example:

- (a) no relative motion - two spike base joints at the same circumference of the spacer;
- (b) axial translation - two base joints of the same spike;

- (c) radial translation - a base joint and a peak joint of a spike;
- (d) constant distance - a base joint and a peak joint of a spike;
- (e) changing distance - two base joints of the same spike; and
- (f) angular translation - when the spacer twists while it expands.

5 In some cases, these various types of motion and relative motion may be combined in a single joint.

Figs. 3F and 3G illustrate a spread view (3F) and an axial view (3G) of a spacer with struts in a collapsed condition. In a spread view, the spacer is axially split, spread open and viewed from above (somewhat like a cylindrical map projection).

10 Figs. 3H-3L illustrate the same spacer in a semi-expanded condition (spread, axial and side views), in which the spikes are extended but the struts are not in their final position.

Figs. 3K-3M illustrate the same spacer in a final expanded condition (spread, axial and side views).

15 This set of figures is somewhat schematic and, in some cases, the correct geometry is somewhat distorted or small features shown in one figure are not shown in another, corresponding figure.

20 In the following description, the motion of the spikes has been separated from the motion of the struts, to simplify the explanation. However, in some embodiments of the invention, what is described herein as separate steps is actually a single combined step in which spikes extend while the struts move to their final positions. In addition, for simplification, spikes are shown as having a zero width and a zero thickness, which is not the case in an actual embodiment.

Fig. 3F is a spread layout of an axial portion of a spacer showing four spikes: AEI, BFJ, CGK and DHL. "AEI" describes a spike in which the two base joints are "A" and "I" and the peak joint is "E". Struts are defined between the peak joints as follows: EF, FG, GH and HE. Point "E" which appears in both sides of the figure, is the same point, duplicated by the layout view.

Fig. 3G is an axial view of the collapsed spacer, in which points A,E,I (and D,H,L, C,G,K, B,F,J) are shown as a single point.

30 Fig. 3H is a spread layout of the spacer after the spikes have been completely extended. Each spike AEI, BFJ, CGK and DHL is shown substantially as a single point. It is noted that the spikes are still axially displaced.

Fig. 3I is an axial view of the spacer, in which the spikes are seen to be extend and the struts interconnect the peaks of the spikes.

Fig. 3J is a side view of the spacer, showing that the struts are in a non-final configuration. It is noted that the extension of the spikes causes the struts to be lifted from the surface of the spacer, so that they are spaced apart from the spacer. The spikes, however, are attached directly to the spacer, at least at one of their ends.

5 Fig. 3K is a spread layout of the spacer after the expansion (and axial contraction) is completed. The spikes are shown as all being at substantially a same axial position of the spacer.

Fig. 3L is an axial view of the spacer, showing the spikes and the struts being fully deployed.

10 ~~Fig. 3M is a side view of the spacer showing that the spikes and the struts are at a same axial position.~~

In the design of a spacer, the properties of the collapsed and/or expanded spacers may be modified by controlling various aspects of the spacer. In particular, one or more of the following aspects may be modified:

- 15 (a) length of collapsed spacer;
 (b) geometry of collapsed spacer;
 (c) length, width, number, density and/or geometry of spikes;
 (d) relative positioning of spikes among themselves and/or the rest of the spacer;
 (e) elasticity, stiffness, plasticity and other mechanical properties of the material(s)
 20 which compose the spacer and/or of the spikes and/or of non-expanding portions of the spacer
 (if any);
 (f) metallurgic and other treatments of the spacer;
 (g) thickness and variations in thickness of the spacer material; and
 (h) coating.

25 In particular, especially as described herein, the above aspects may be different for different parts of the spacer and/or for different spikes. Alternatively or additionally, these aspects may vary temporally, for example, elasticity varying as a result of gradual "learning" of the spacer.

30 In a preferred embodiment of the invention, the spacer is manufactured by laser cutting or e-beam cutting a metal tube.

In some preferred embodiments of the invention, selected portions of the spacer are metallurgically treated. In one embodiment, a portion of the spacer is annealed by heating (not cutting) that portion, for example, with a laser, an e-beam or a plasma beam. Alternatively or additionally, the rest of the spacer is protected from the heating of the beam, for example using

an external or internal heat dissipating mold or by using a mask, which block heat-causing beams. Possibly, the mold comprises a heat conducting material, such as copper or aluminum. Alternatively or additionally, the mold includes active cooling, for example water, oil or gas cooling or cooling by sublimation of the mold material.

- 5 In a preferred embodiment of the invention, the annealing is used to make points which twist or bend more malleable, while maintaining non-distorting portions (such as spike legs and struts) more rigid.

Other possible types of local metallurgic treatments (possibly utilizing a mold) include, localized ablation (not cutting through), deposition of ions, local sintering, local welding, 10 drilling of small holes and/or attaching additional thickness of material.

In preferred embodiments of the invention, one or more of the above aspects and/or design properties of the spacer are modified, especially as described herein, in order to achieve one or more of the following desired spacer properties:

- (a) resilience profile of the spacer, preferably as a function of direction of force application;
- (b) collapse profile, i.e., how much radial force will cause the spacer to (typically undesirably) collapse and how much will it collapse;
- (c) resistance to axial, rotational, radial, twisting and/or flexing motion, prior, during and/or post insertion;
- 20 (d) amount of conformance to body-structure geometry and ability to adapt, while being expanded and/or after being in place, possibly requiring variations in properties over the spacer;
- (e) type and/or extent of contact with bone, especially with respect to digging into bone;
- 25 (f) surface area, especially with respect to adherence to new bone growth and/or danger of irritating the body;
- (g) ease and/or method of insertion, expansion, bone anchoring, adjustment and/or retraction;
- (h) size of playground, i.e., the allowed error in matching a particular spacer to a 30 particular medical situation; and
- (i) support and/or enhancement of new bone growth.

Fig. 4A shows a flat projection of a spacer having a square cross-section when expanded, in an un-expanded configuration, in accordance with a preferred embodiment of the invention. Fig. 4B shows a flat projection of the spacer of Fig. 4A, in an expanded

configuration. Fig. 4C shows a perspective projection of the spacer of Fig. 4A, in an expanded configuration. The above figures also include measurements for a preferred embodiment of the invention. For example, a length of 114 mm (un-expanded) and 23.9 mm (expanded), a diameter of 4 mm (un-expanded) and 14 mm (expanded) - each side, the material may be 5 titanium, with a thickness or 0.5 mm. Alternatively or additionally, the material may comprise Nitinol (NiTi), Titanium, Surgical Stainless Steel, plastic and/or various alloys, such as bio-inert metal alloys.

In a preferred embodiment of the invention, the spacer surface is smooth. Alternatively or additionally, at least some of the spacer surface is rough, to encourage bone growth and/or 10 adherence. Alternatively or additionally, at least some of the spacer surface includes small bars, to engage the bone and or soft tissue. In some embodiments, only the tips of the spikes and/or areas near the tips have non-smooth surfaces.

Fig. 4D illustrates a spacer configuration in which one spacer 142 is expanded inside another spacer 140, for example, to increase the total stiffness of the spacers. In a preferred 15 embodiment of the invention, spikes 146 of inner spacer 142 match the hollows of spikes 144 of outer spacer 140. Alternatively or additionally, spacer 140 may function as a mold for expansion of inner spacer 142 (for example as in Fig. 2G). In some embodiments, this may require the spikes to be sharper on the inner spacer and/or the internal structure of the outer spacer to be more guiding, such that the expanding inner-spacer spikes are suitably guided.

20 Alternatively, spikes 146 may not match spikes 144, for example as shown by dotted line 148. Preferably, the two spacers are selected so that none of the spikes match or so that spikes only on one side and/or one portion of the spacers match.

Generally, the inner spacer is inserted into the first spacer if it is determined that the 25 stiffness of the first spacer is too small. In some cases this may be the result of the expansion of spacer 140 being limited, so the base of spikes 144 is wide (resulting in a weak spike). Preferably, the inner spacer is inserted during the same procedure. Alternatively, an inner spacer may be inserted later, possibly a few days after the first procedure is completed.

Alternatively or additionally to inserting spacers one inside the other, multiple spacers 30 may be used for a single inter-vertebral space (or other body space) in other configurations. In one configuration, a disc is replaced by two parallel spacers, on one each side of the spinal column. Generally, the two spacers do not touch. Alternatively, the two spacers may be bent and touch at one or two of their ends. In another example, two, three, four or more spacers may be inserted to be coaxial, for example in series and/or to be co-planar, for example side-by side. Typically, the spikes on the two spacers interlock, at least as a result of friction and/or

inherent flexibility of the spikes. In some cases, the spike spacing and/or spike shapes may be selected to encourage or discourage such an interlock. When the spacers are inserted in series, the spacers may include forward folding and/or rear-folding spikes, to encourage interlocking. The multiple spacers may be expanded in parallel. Alternatively, a second spacer is expanded only after a first spacer is already expanded. Possibly however, the expansion of the first spacer may be adjusted to match the expansion of the second spacer. In some cases, the spacers are not coaxial, for example their axes being somewhat perpendicular, for example as described with reference to Fig. 2P.

Alternatively or additionally, multiple spacers may be used to fill a space where, possibly, a single straight spacer would have sufficed. However, in some cases better control over the spacing and/or spinal support are achieved using multiple spacers.

In one preferred embodiment of the invention, the spacers may comprises different materials, for example to provide composite and/or locally adapted mechanical characteristics. Alternatively or additionally, different materials may be used to provide a small electrochemical potential between the spacers, for example to encourage bone growth. Alternatively or additionally, a small voltage potential may be provided using a two layer material to construct the spacer, with an isolator between the spacer layers. Possibly, a voltage source is connected between the spacers, with the circuit closed by body fluids.

Fig. 5 illustrates a spacer 150 in which slits 152 are defined on the spacer in a spiral pattern. In this embodiment, spacer 150 is expand by applying a rotational force to the spacer, rather than an axial force. In a preferred embodiment of the invention, one end of the spacer is modified to grip bone, to provide a suitable anchor for bone, for example as exemplified by a pair of extensions 154. In a preferred embodiment of the invention, extensions 154 fold out, for example as shown by dotted line 156, to radially grasp the bone prior to the expansion of the spacer. Preferably, the extensions are made of an elastic or super-elastic material which is maintained in an axial configuration until the spacer is inserted in place. Such anchoring may also be useful for other embodiments of the invention, described herein. However, in other preferred embodiments of the invention, no bone anchors are provided, as the spacer can expanded in place without anchoring.

Figs. 6A-6V illustrate variants of spikes and/or spike orientations and/or spike layout patterns, in accordance with alternative preferred embodiments of the invention.

Figs. 6A-6K illustrate various spike side profiles (i.e., viewing from the side of the spacer), in accordance with preferred embodiments of the invention. Generally, the profiles on both sides of the spike match. However, in some preferred embodiments of the invention, the

profile may vary over the width of a spike. Thus, a projection of the spike onto a plane perpendicular to the spike and parallel to the spacer axis may yield a square shape, but may also yield a triangle shape or a more complex shape, for example an hourglass.

Fig. 6A illustrates a triangular profile, however, the tip of the spike will usually be
5 rounder.

Fig. 6B illustrates a rectangular profile.

Fig. 6C illustrates an inverse triangular profile.

Fig. 6D illustrates an hourglass profile. Profiles 6C and 6D have the possible advantage of having a large area in contact with adjacent bone. A possibly advantage of the spike of Fig.
10 6D is a resistance to collapsing and the possibility of any collapsing being partial, whereby the spike becomes shorter, rather than completely collapsing. Another advantage of these inverted spikes is that their inverted bases abut against adjacent spike's bases, possibly stiffening the spacer.

Fig. 6E and Fig. 6F. illustrate two level spikes. One possible advantage of such spikes
15 is a is that the upper level spike portion can collapse without affecting the lower level spike portion. Another possible advantage is providing a lower portion of a spike which can resist large loads and an upper portion of a spike which better engages the adjacent bone tissue.

Fig. 6G illustrates an asymmetric spike. In addition, the other spikes described herein
may be constructed to be asymmetric.

20 Fig. 6H illustrates a spike having portions which are below a surface of the spacer.

Fig. 6I illustrates a spike which overhangs and which is at a non-normal angle to the spacer. The angle maybe between 89° and 20° , for example about 40° about 60° , about 70° or about 80° . Alternatively or additionally, the spike profile may be curved.

Fig. 6J illustrates a spike in which only one arm of the spike is connected to the spacer.
25 This spike form is preferably manufacture by pre-loading such a strip to be extended and maintaining the spike in a flat position until the spacer is inserted and/or axially contracted. In a preferred embodiment of the invention, when the spacer is shortened, the spike element is above the surface of the spacer and, so, is guided by the surface of the spacer to a more extended configuration. Possibly, the surface of the spacer across the spike protrudes from the
30 spacer, to further urge this spike in a radial direction (rather than allowing axial translation).

Fig. 6K illustrates a spike including a plurality of sub-spikes.

Figs. 6L-6N illustrate (using an axial view) variations in an angle between the spike and the spacer, in a plane perpendicular to the spacer axis. Although right-leaning spikes are shown, in some preferred embodiments of the invention left leaning spikes are used.

Fig. 6L illustrates a spike that is normal to the spacer surface.

Fig. 6M illustrates a spike which is at an intermediate angle to the spacer surface, for example between 10° and 80° , for example about 30° , about 50° or about 70° .

Fig. 6N illustrates a spike which is parallel to the spacer surface.

5 Figs. 6O-6S illustrate (using an axial view) variations in a spike profile in the plane perpendicular to the spacer axis. It is noted that variations in this profile of the spike may be affected by cutting the spike-defining slit in the form of the desired profile. Preferably, portions of the surface of the spacer are removed so that the spike defining region has a rectangular form. However, this is not required. Only the front profiles are shown. Generally,
10 the back profiles match the front profiles. However, the front and back profiles may be different, in some preferred embodiments of the invention.

Fig. 6O illustrates a rectangular profile.

Fig. 6P illustrates a trapezoid profile.

Fig. 6Q illustrates a triangular profile.

15 Fig. 6R illustrates an angled profile.

Fig. 6S illustrates a bent profile.

Figs. 6T-6V illustrate spread layouts of spikes on the surface of a collapsed spacer, in accordance with various preferred embodiments of the invention. In the illustrations, the spacer is expanded, axially slit, flattened, and viewed from above. The spike locations are
20 indicated as circles, even though, they may have other forms when viewed from above, typically that of a rectangle. The radial and/or axial and/or spatial density of spikes may vary in some embodiments from what is shown in the figures.

Fig. 6T illustrates an alternating spike pattern, in which the spikes are arranged in rings which have an angular offset between them. The number of spikes per ring may be the same
25 for all the rings or may be different, periodically and/or as a function of axial position. The pattern may also be viewed as a hexagonal grid layout.

Fig. 6U illustrates an even spike distribution, arranged on grid vertexes of a rectangular grid.

Fig. 6V illustrates a spike distribution in which the axial spike density varies as a
30 function of the axial location. Alternatively or additionally, the radial density may vary as a function of the axial position. Alternatively or additionally, the radial density may vary as a function of the radial position. Alternatively or additionally, the axial density may vary as a function of the radial position.

Figs. 6W and 6X illustrate spikes that have more than two legs. In particular a spike 300 of Fig. 6W has three legs: 302, 304 and 306. In Fig. 6X a spike 308 also has three legs: two legs 314 and one leg 312. A bar 310 connects the two legs 314 to leg 312. It is noted than when spike 308 is extended (perpendicular to the figure), bar 310 twists, rather than bending as in some of the previously described spikes. An additional type of deformation available is a pivot type deformation, in which a joint is defined in the spacer. Possibly, such a joint is defined by using a different material for the joint than for the rest of the spacer. These types of deformations (bending twisting and pivoting) and/or other deformation types may also be used for defining struts and wires. It is noted with respect to Fig. 6X it is noted that the base of spike 308 may have a zero width, for example if leg 312 moves axially to be between legs 314.

Figs. 6XA-6XC illustrate a lift-up mechanism, whereby a spike (in this example a flat top spike) is lifted up from the plane of the unexpanded spacer. Fig. 6XA is a side view, Fig. 6XB is a perspective view and Fig. 6XC is a plan layout. Referring to Fig. 6XB and to Fig. 6XG (below), when two ends 315 and 316 of the spacer portion are brought together, legs 320 bend and a portion 318 of the spacer is lifted out of the spacer, in the direction of the arrow. In a preferred embodiment of the invention, the legs 320 are weakened at their ends so that the legs bend only at the weakened areas and/or in a direction dictated by the weakening.

Figs. 6XD-6XH illustrate an alternative lift-up mechanism, in which a plurality of legs 320' and a lifted up portion 318' are substantially in a same hemisphere of the spacer, so that two symmetrically opposing lift-up spikes may be fabricated on a single spacer segment. Fig. 6XH is a plan layout of the spacer; Fig. 6XD and 6XE are side views of the collapsed spacer; and Fig. 6XF is a perspective view of the collapsed spacer. Fig. 6XG, which is equally applicable to Figs. 6XA-6XC illustrates a side view of an expanded spacer, with portion 318 lifted up form the spacer.

One advantage of the lifted up spikes is that they may easily be formed of curved pieces of material, since the lifted up part is not bent.

Figs. 6XI-6XL illustrate (using a side view, with an axial portion of the spacer removed) examples of weakening of spacer material to aid in achieving some exemplary spikes profiles of those shown in Figs. 6A-6K. The weakening illustrated are etching and/or cutting of material in a direction perpendicular to the spacer surface. However, weakening may also be achieved using other means, for example, chemical or metallurgic treatment or by drilling small holes. Addition, the direction of the weakening may be at other orientations, for example along the surface of the spacer (as in Fig. 6XA) or at an angle thereto. Additionally or alternatively, the weakening and/or strengthening of the spacer is applied to provide a

preferential distortion direction. Fig. 6XI shows a weakening pattern which aids in achieving a symmetric spike. Fig. 6XJ shows a weakening pattern which aids in achieving an asymmetric spike. Fig. 6XK shows a weakening pattern which aids in achieving a flat top spike. Fig. 6XL shows a weakening pattern which aids in achieving an arc shaped spike.

5 Although the above figures illustrate individual spacer geometries, in some preferred embodiments of the invention, geometries from two or more of the above figures may be combined in a single spacer, possibly in a single spike. In addition, the particular spike configuration selected may depend, *inter alia*, on the intended use of the spacer. In particular, spike combinations and/or configurations may be selected responsive to a desired interaction
10 between spikes, for example adjacent spikes leaning on each other or engaging each other.

Fig. 7 schematically illustrates protrusions on a spacer portion 400, in accordance with a preferred embodiment of the invention. The portion is shown in a side view and in a perspective view. Portion 400 includes a spike 402 and a base portion (in some cases a ring segment) 410. In a preferred embodiment of the invention, a protrusion 404 and/or a protrusion
15 406 are provided to increase the stiffness of spike 402 and/or prevent its collapse under pressure. In the example of protrusion 404, spike 402 cannot fold to the right, because protrusion 404 is blocking the movement. In the example of protrusion 406, such movement is again blocked. Protrusion 406 may have an alternative or additional function of stiffening the spacer by filling in gaps between spike 402 and a neighboring (axially and/or radially offset)
20 spike 408.

In a preferred embodiment of the invention, the protrusions are created by a variation in the thickness of the spacer. Alternatively, a protrusion may comprise a portion of the tube which folds out (or in). Preferably, the portion is manufactured to be in an out position and is maintained in an "in" position, while the spacer is collapsed, for example using an external collar. Alternatively, the protrusion may be created by the expansion, for example the
25 protrusion comprising a small spike.

Fig. 8A illustrates a spacer 420 in which axial shrinkage of the spacer is limited by the design of a tube portion 422 of the spacer, in accordance with a preferred embodiment of the invention. When spacer 420 is expanded, tube 422 axially contracts and spike 424 is extended.
30 Additionally tube portions on either side of the spike advance towards each other. These portions are marked as a tab 428 and a tab 426 in the Figure. It is noted however, that only one such tab is required, since the other tube portion may be flush with the spike base or even back therefrom. When the two tabs meet, further axial contraction is impossible or is severely restricted. Further contraction, if it were to occur, would require either that one of the tabs

collapse or that one tab travels over the other tab. As noted above with respect to Fig. 6J, such a tab may be useful to guide the extension direction of a spike.

In a preferred embodiment of the invention, an adjustment to mechanical characteristics of a spacer, for example tension, is achieved by moving the one tab relative to the other, for example using an externally applied needle, to allow them to continue their axial movement. Additionally, one such axial motion is allowed, the spacer may be further expanded.

It is noted that the final length and/or shape of the expanded spacer and/or individual spikes thereon may be considerably influenced by tabs 426 and 428. In a preferred embodiment of the invention, a spacer is adapted for a particular use by removing and/or bending such tabs so that they do or do not impede axial compression. In one example, such tabs may be removed in an operating room by a surgeon, after he makes final measurements on an x-ray image. In another example, if a spacer did not fit, the spacer is removed, adjusted and reinserted (or a new, adjusted, spacer is inserted).

In a preferred embodiment of the invention, the distribution of tabs 426 (and 428) is even over the length of the spacer. Alternatively, an uneven axial distribution is provided. Alternatively or additionally, an uneven radial distribution may be provided. Alternatively or additionally, the length of the tabs is different at different parts of the spacer. It is noted that an un-even distribution of tabs on the spacer may cause the expanded spacer to assume a bent configuration and/or for spikes to have un-even lengths.

Fig. 8B illustrates an alternative embodiment of the invention wherein a portion of a spacer 430 collapses upon itself to limit axial contraction of the spacer. In a preferred embodiment of the invention, such collapsing is achieved by weakening a strip of spacer 430 at a plurality of locations, for example those indicated by reference number 436. Preferably, the weakening comprises a thinning of the material on the side of the fold. Alternatively or additionally, the portion is pre-formed to be in a shape of a wave, and maintained in an uncollapsed state either by the un-extended spikes (e.g., before they are plastically deformed) or by a restraining device (for example as described above with reference to Fig. 2). Dotted line 438 indicates an extent of a spike when the spacer is expanded.

In another embodiment of the invention, a spike extends into the lumen of the spacer instead of out, thereby restricting axial contraction of the spacer.

In the embodiments shown in Figs. 8A and 8B, the axial contraction restriction elements appear to be positioned instead of a spike. Although this is possible, it is not required. In alternative embodiments of the invention, at least some of the tabs and/or wave-

folded tube portions may be radially located between spikes, for example, a radius including four spikes and four axial contraction restriction elements. Alternatively or additionally, a tab may be defined as part of the spike itself, for example as indicated by dotted lines 427 and 429 in Fig. 8A.

5 Fig. 9A illustrates an excavating tool 450, in accordance with a preferred embodiment of the invention. In a preferred embodiment of the invention, tool 450 is used to pulverize a disc, prior to insertion of a spacer. Tool 450 preferably comprises a shaft 452 and a tip 454. In a preferred embodiment of the invention, tip 454 comprises a radially expandable element, as described above with reference to a spacer. Thus, the tool can be inserted in a collapsed 10 diameter and expanded only in the space which is to be excavated. When shaft 452 is rotated, tip 454 rotates and pulverizes the disc material.

15 In a preferred embodiment of the invention, the entire tool 450 is made of a single material. Alternatively, a material with a different hardness, stiffness and/or abrasion resistance may be used for the tip. Alternatively or additionally, the sides and/or ends of the spikes in tip 454 may be sharpened and/or coated with an abrasive material, to assist in the pulverization.

20 Fig. 9B illustrates the tool of Fig. 9A, in which bent configurations are shown using dotted lines, in accordance with a preferred embodiment of the invention. Typically, the geometry of the volume to be excavated does not have a circular cross-section. In a preferred embodiment of the invention, shaft 452 may be bent, at least in a vicinity 462 of tip 454, to allow a greater reach for tip 454. Alternatively or additionally, tip 454 itself may bend. In a preferred embodiment of the invention, the bending is achieved by inserting a bent stylet 458 into a lumen 456 defined in shaft 452. Alternatively, vicinity 462 is flexible and tip 454 is allowed to freely bend.

25 In a preferred embodiment of the invention, stylet 458 is not rotated with shaft 452, so that tip 454 is maintained in a constant angle, for example maintaining tip 454 in a position 460. Alternatively, the stylet and the shaft are rotated in synchrony.

30 Alternatively or additionally, tool 454 may be bent by axial contraction thereof. As indicated above, the axial contraction may be uneven on the two sides of the spacer, for by reason of uneven distribution of tabs 426 (Fig. 8A). In one example, a regular axial contraction yields a straight tool tip. When the axial contraction is increased (e.g., and more spikes are expanded and/or more tabs abut), the tool bends in one direction, and when the contraction is further increased, the tool bends in another, possibly opposite, direction.

A lumen in tool 450 may have other uses, in some preferred embodiments of the invention. These uses may use the same lumen as lumen 456 or may require a separate lumen. The uses may be applied while the shaft is rotating and/or while the shaft is at rest. One use of such a lumen is to vacuum out the pulverized disc material. Another use is for injecting fluids, for example, pharmaceuticals, tissue softening materials and/or medical imaging contrast materials. Alternatively or additionally, the lumen may be used to provide a cutting action, for example by providing laser light, a knife edge, cryosurgery tools, RF coils or electric cutters through the lumen. Alternatively or additionally, a high pressure flow of abrasive material may be provided. Alternatively or additionally, the lumen may be used to provide endoscopic

10 surgery tools and/or tissue connectors, such as clips or staples. Alternatively or additionally, the lumen may be used to provide an imaging means, such as an optical viewing means or an ultrasonic viewing means. Alternatively or additionally, a spacer may be provided and/or expanded and/or collapsed through the lumen. Optionally, in one preferred embodiment of the invention, the tool itself may be further expanded and used as a spacer, after the disc is
15 removed.

The above uses of a lumen may also be practiced on a spacer, in accordance with some preferred embodiments of the invention. In particular, a tool 450 may be provided through a spacer. In another example, a second spacer may be inserted past a first spacer, by passing a member 60 of the second spacer through the expanded spacer.

20 As described above, the expandable spacer is especially suitable for spinal fusion. However, a similar geometry device may have other uses. One type of usage is as a bone fixation device, for example fulfilling the general requirements described in the above reference PCT publication WO 98/38918. Fig. 10A illustrates a bone 700 with a fracture location 702 into which a spacer 704 (in this example being used as a bone fixator) is being
25 inserted. An optional elongate member 706 may be a guide or may for an extension of the spacer, for example as described herein above with reference to Fig. 2. It is noted that the spacer of the present invention, in some embodiments thereof may be inserted through a small hole in a bone, possibly without open surgery. Optionally, the spacer includes an outside thread, at least at its tip, so that the spacer can be screwed into the bone. Preferably, the spacer
30 may also be removed through the same or a new hole made in the bone, preferably without requiring an open surgical incision. Optionally, as shown in Fig. 10B, when the insertion of the spacer is completed, a flared opening 708 is maintained in the bone, possibly by an extension of the spacer, to aid in adjusting and/or removing the spacer. Alternatively, it is noted that the spacer does not usually block a large volume of the bone, so it may not be

required to remove it. Fig. 10C illustrates the insertion of a spacer into a bent bone 710, for example a rib. Also, it is noted that such a spacer may be inserted into a small bone, for example a finger bone.

Fig. 11 is an exploded view of a dental implant 600 in accordance with a preferred embodiment of the invention. A tooth is missing in a jaw 601, leaving behind a hole 602. In a preferred embodiment of the invention, an expandable spacer 604 is inserted into the hole and expanded therein, to form a support for a dental cap 606. Preferably, a filler material, such as powdered bone or tooth material is used to fill hole 602. Alternatively or additionally to forming a complete support for a dental cap, an expandable spacer may be used to fill-in a space between a support and the walls of hole 602. Alternatively or additionally, an expandable spacer may be used to replace a single root of a multi-root natural tooth. It is noted that bone tissue, tooth material, nervous tissue and/or blood vessels may grow into the hollows of spacer 604. Optionally, an inner support is also inserted into the spacer, to strengthen it, for example a screw as described above with reference to Fig. 2.

Figs. 12A-12C illustrate the use of an axially contracting tissue fastener 610, in accordance with a preferred embodiment of the invention. A tissue 612 is to be fastened to tissue 614. A tip 611, preferably sharp, possibly barbed or curved, of fastener 610 preferably penetrates the two tissues, as shown in Fig. 12A. It is noted that fastener 610 may be narrow and/or flexible; thus being suitable for application using a catheter, an endoscope and/or using an external syringe-like device.

In Fig. 12B, a first set of spikes 616 and/or a second set of spikes 618 are preferably extended, to stop the tissues from moving away from each other. In the case that only one set of spikes is extended, for example spikes 616, the fastener may be axially moved, for example in the direction of arrow 620, in order to bring the two tissue together. It should be noted that tissue 612 and/or tissue 614 may have a considerable thickness. In such a case the spikes will preferably expand into the tissue, instead of behind it as shown in Fig. 12B. However, the function of engaging the tissue will preferably be performed.

In Fig. 12C, the rest of fastener 610 is axially contracted, bringing the two tissues in close proximity. The width of an intermediate section 622 of the fastener may depend on the distance between the tissue when spikes 616 and 618 are expanded and/or it may depend on whether or not the fastener is moved during the procedure. However, in general, the distance between the two tissues will be considerable smaller than in Fig. 12A and the two tissue will be coupled by section 622, preferably to allow little or no relative motion. Optionally, the fastener (or a spacer, as described above) is formed of a plurality of links which can rotate one

relative to the other. Thus, the two attached soft tissue can rotate one relative to each other, if each is grasped by a different link of the spacer. In a preferred embodiment of the invention, each such link may be expanded or collapsed separately.

As described above, the spikes of fastener 610 are preferably expanded in a certain order. However, the action of Figs. 12A-C will occur also if all the spikes are expanded at the same time. Generally, after a short axial contraction, spikes 616 will expand enough so that they will not retract through the hole made in tissue 612 by tip 611. Although further axial contraction will increase the tension on the hole (by stretching/moving tissue 612) it will also increase the spike size, so retraction of the spikes is unlikely.

In a preferred embodiment of the invention, exact placement of fastener 610 is not required, since once tissues 612 and 614 are skewered by fastener 610 and are each located between two spike positions, further axial contraction of the fastener will invariably engage the tissues and bring them together.

In some preferred embodiments of the invention, the spikes in section 622 are longer than in the rest of fastener 610, allowing a greater axial contraction. It is noted that, in some applications, it is desirable to allow some "free" space between the fastened soft tissues.

In a preferred embodiment of the invention, once the process of Figs. 12A-12C is complete, fastener 610 is disengaged at its end 624 from a member (not shown) which was holding it in place. Alternatively, fastener 610 comprises an elastic or super elastic element which is injected into a tissue and allowed to self-expand, without being held by a member. Alternatively fastener 610 may comprise a portion of a continuously extruded fastener. When required to fasten soft tissue, a short segment of the fastener is used as in Figs. 12A-12C and then the remainder of the fastener is cut off. Thus, multiple fastening activities may be performed with a minimum required diameter and a minimum of tool exchanging and/or toll motion.

As an alternative embodiment (not shown) a single spike may span spikes 616 and 618. Referring back to Fig. 2K (multi-sub-spike spike example) a single spike may include two or more sub spikes, for example a sub-spike 616 and a sub-spike 618. When such a single spike partially extends, the two sub spikes engage the soft tissues. As the spike continues to extend (axial compression of the fastener) each of the sub spikes increases in radial extent and is brought closer together. Such behavior may be controlled by suitable weakening of the spikes, as described above, for example with reference to Fig. 6XI, noting however, that if a spike is weakened by different amounts in different locations, the weaker location will typically fold first and then the strongest location, when axial compression is applied.

Alternatively to fastening soft tissue to soft tissue, a fastener similar to fastener 610 may be used for attaching soft tissue to bone. In one example, if tip 611 comprises a bone anchor, the process of Figs. 12A-C may be performed to attach tissue 614 to a bone 612, except that there is generally no need to expand spikes 616 in the bone. Alternatively, spikes 5 616 are expanded a small amount, to better hold the bone. Alternatively, spikes 616 are expanded by a large amount, for example if tip 611 passes through a cortical portion of the bone into a trabecular portion thereof.

Additionally or alternatively, to fastening soft tissue to bone, a similar fastener may be used to attach a bone to a bone and/or to apply attractive forces between two bones. In this 10 embodiment, it may be unnecessary for the spikes to extend when the spacer is axially shortened. In a preferred embodiment of the invention, a spike shape as shown in Fig. 6K is used, in which the spikes extend a minimal amount. Alternatively, the spikes may "extend" into the lumen, preferably using a spike profile which is the inverse of that of Fig. 6K.

Another possible use of the expanding spacer is to fill intra body cavities and/or 15 change mechanical properties of body tissues, for example stiffness, elasticity, minimum compressed dimension. For example, such a spacer may be used to stiffen a intra-vertebral disc. Additionally or alternatively, such a spacer is used as a framework for new tissue growth. Additionally or alternatively, such a spacer is used to enhance drainage. Changing the 20 mechanical properties of body tissue may also be used for cosmetic purposes, for example to reduce sagging and to disguise flabby flesh.

In some such cases, the spacer is composed, at least in part, of softer, thinner and/or more flexible materials than described with reference to Figs. 4A-4C. In one example, the spacer is made of plastic. In another example, the spacer comprises polymer coated metal.

Another possible use of such a spacer is for opening crushed or otherwise blocked air 25 passageways. One advantage of some embodiments of the above spacer is that they are inherently non-blocking, if for example a spacer fails to open properly.

In a preferred embodiment of the invention, a spacer, for example as described above, can be controlled from outside the body, after it is inserted. In one example, referring back to 30 Fig. 2J, screw 124 may be turned by coupling a magnetic force from outside the body, for example if a small permanent magnet is coupled to the screw. When a strong permanent magnet is rotated outside the body, torque is applied to the small magnet, turning the screw. In another example, externally applied magnetic and/or electric fields may be used to control a pressure valve, which valve allows pressurized fluid to inflate or deflate a balloon, thereby axially and/or radially expanding or collapsing the spacer. In some embodiments, the control

of spacer expansion uses logic (electrical or mechanical) which is integrated into the spacer, for example, to periodically axially compress the spacer. The power and/or control signals may be supplied from inside the body or from a power source (or computer) outside the body.

It will be appreciated that the above described apparatus and methods of expandable inserts may be varied in many ways. In addition, a multiplicity of various features, both of methods and of devices have been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every similar preferred embodiment of the invention. Further, combinations of the above features are also considered to be within the scope of some preferred embodiments of the invention. It should also be appreciated that many of the embodiments are described only as methods or only as apparatus. The scope of the invention also covers machines for creating the devices. In addition, the scope of the invention includes methods of using, constructing, calibrating and/or maintaining the apparatus described herein. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like means "including but not limited to".

CLAIMS

1. An expandable spacer, comprising:

5 a tube having a surface and an extent,

wherein, said surface defines a plurality of slits, said plurality of slits defining a second plurality of spikes, such that when said tube is axially compressed, said spikes fold out of said surface.

10 2. An expandable spacer comprising a tube having an extent and a diameter and defining a plurality of slits thereon, wherein, said spacer is designed to have two configurations, a first configuration in which said extent is long and said diameter is small and a second configuration in which said extent is shorter and said diameter is larger.

15

3. An expandable spacer substantially as described and shown.

4. A spacer, comprising:

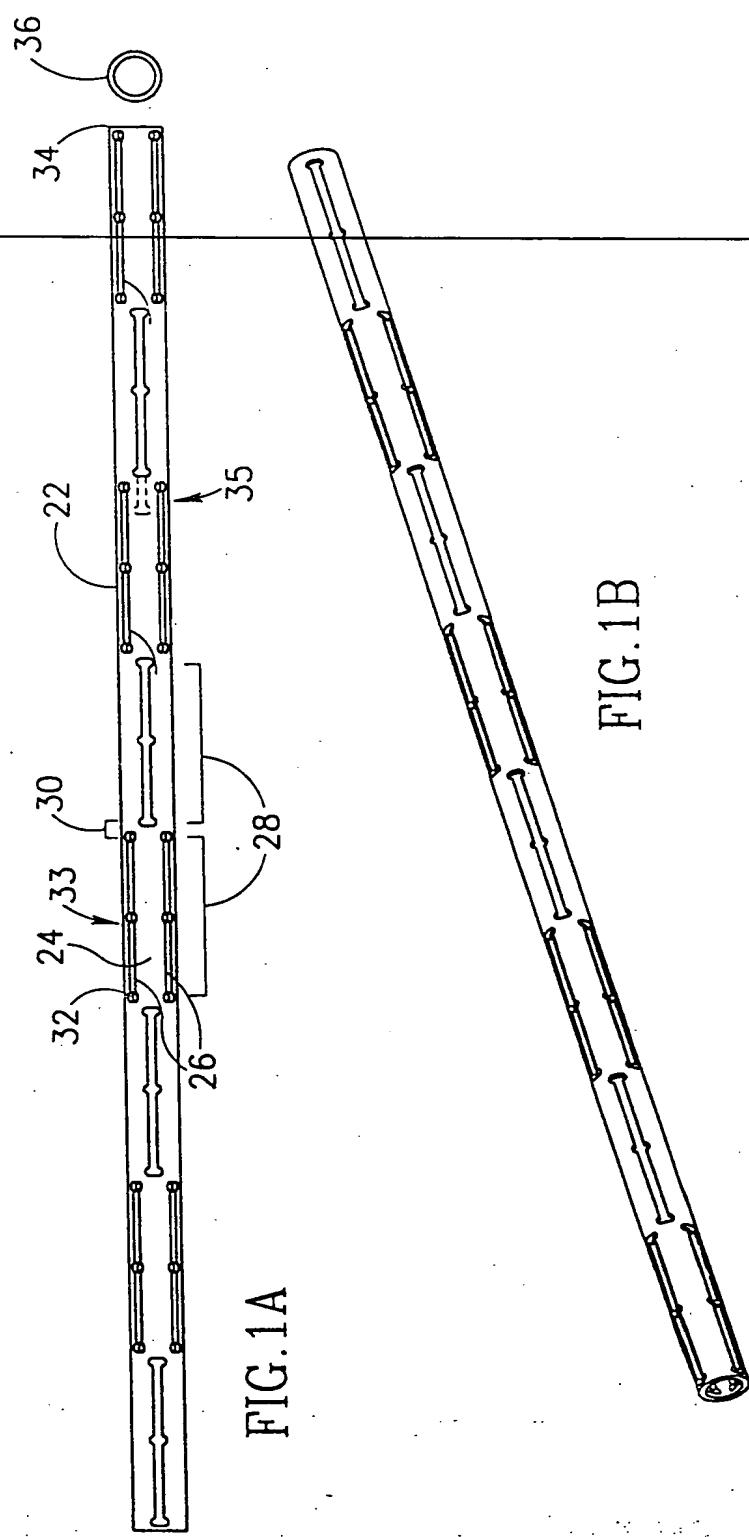
an elongate body having a surface and having a cross-section at a portion thereof; and
20 a plurality of spikes radially extending from said body,

wherein, said spikes are dense on at least 50% of said body, including said portion, wherein said dense spikes define a cross-section having a diameter at least three times a diameter of said body cross-section and wherein said spikes are formed of said surface.

25

For the Applicant,

Fenster & Co. Patent Attorneys, Ltd.
c:110/00625



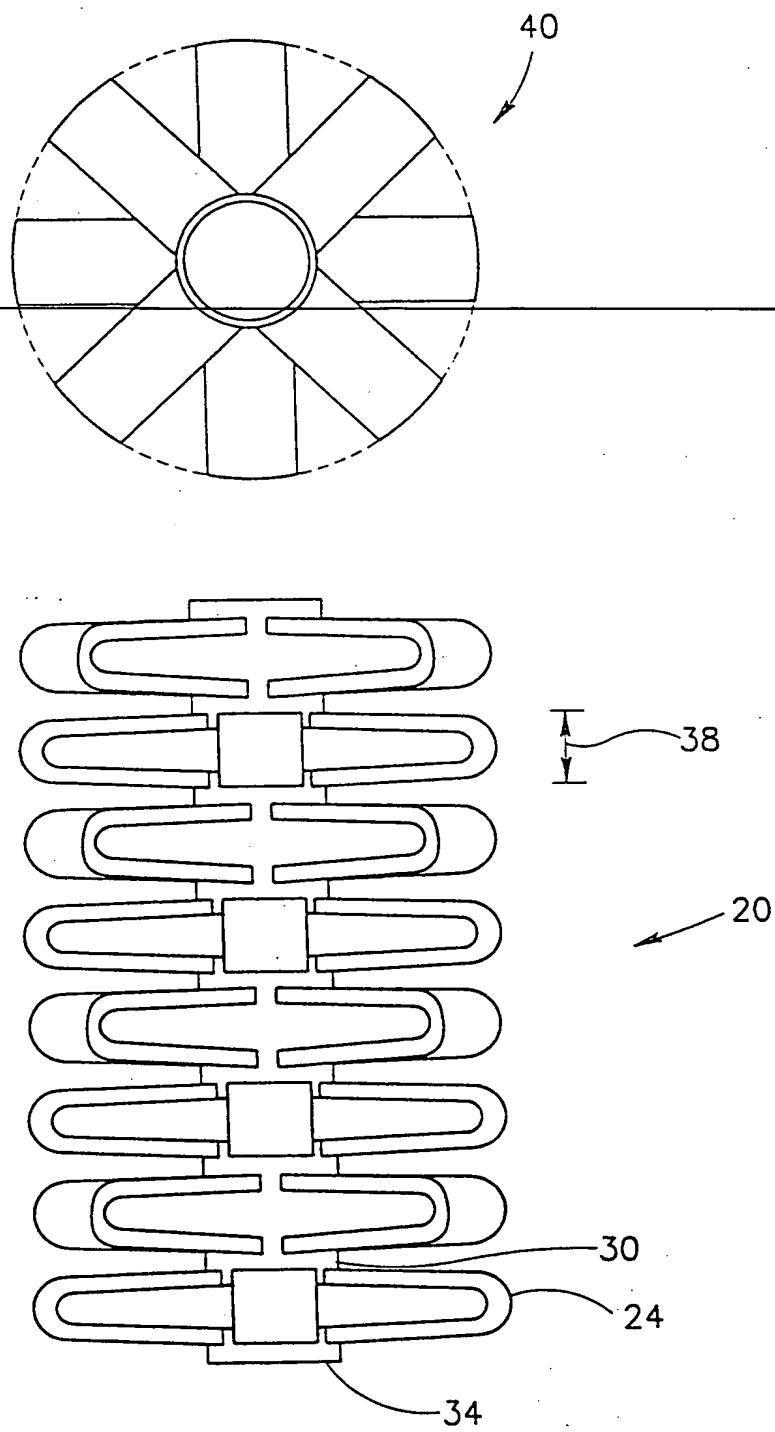


FIG.1C

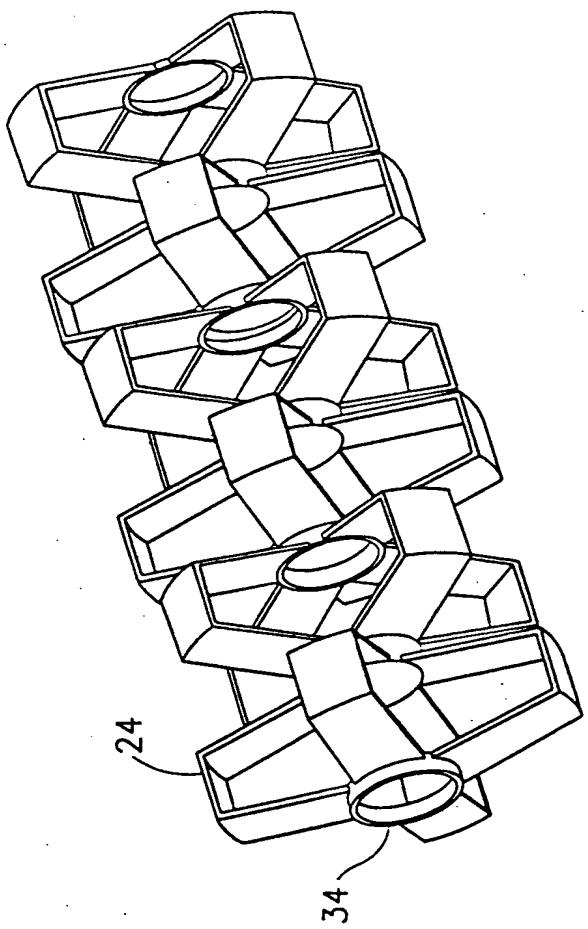


FIG. 1D

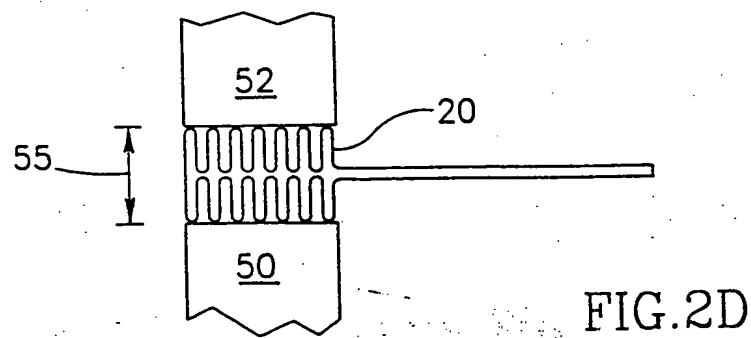
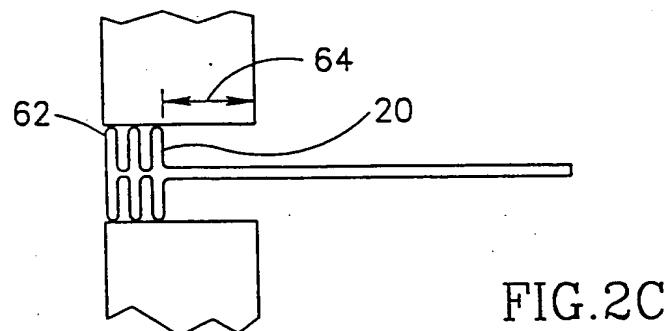
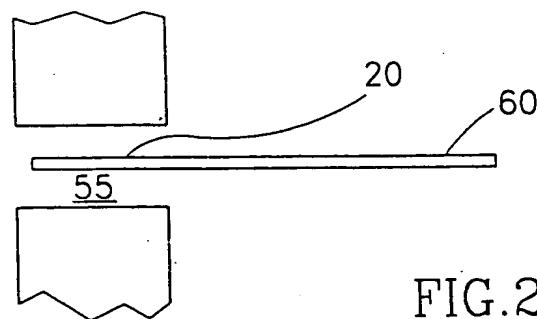
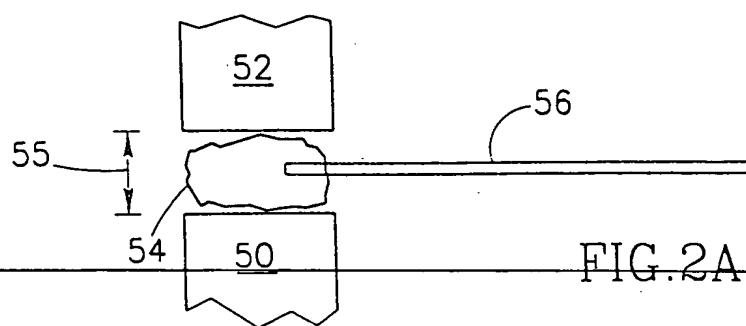


FIG.2E

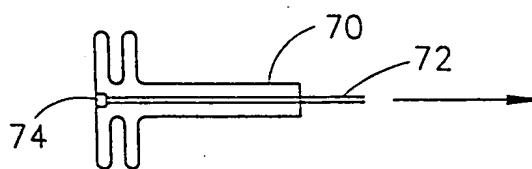


FIG.2F

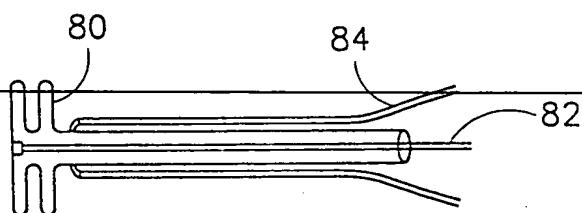


FIG.2G

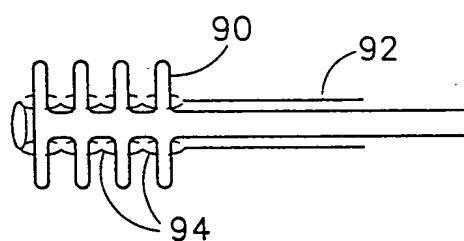


FIG.2H

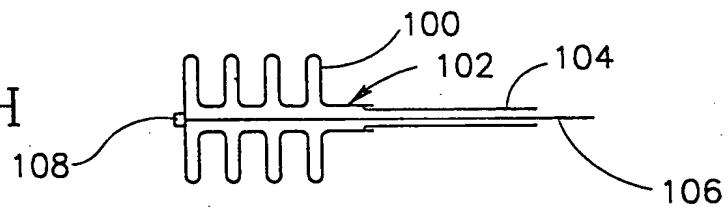


FIG.2I

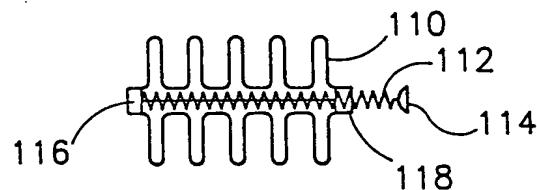
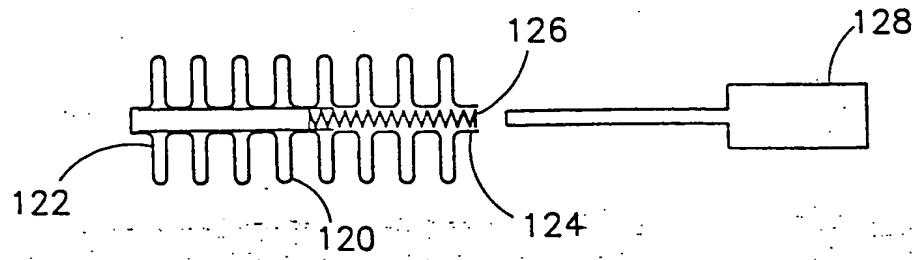


FIG.2J



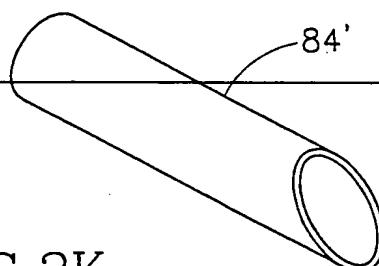


FIG.2K

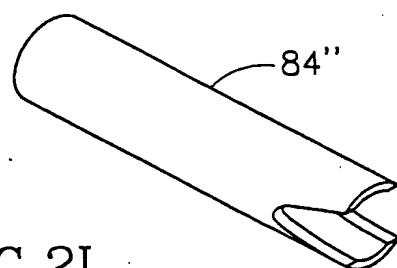
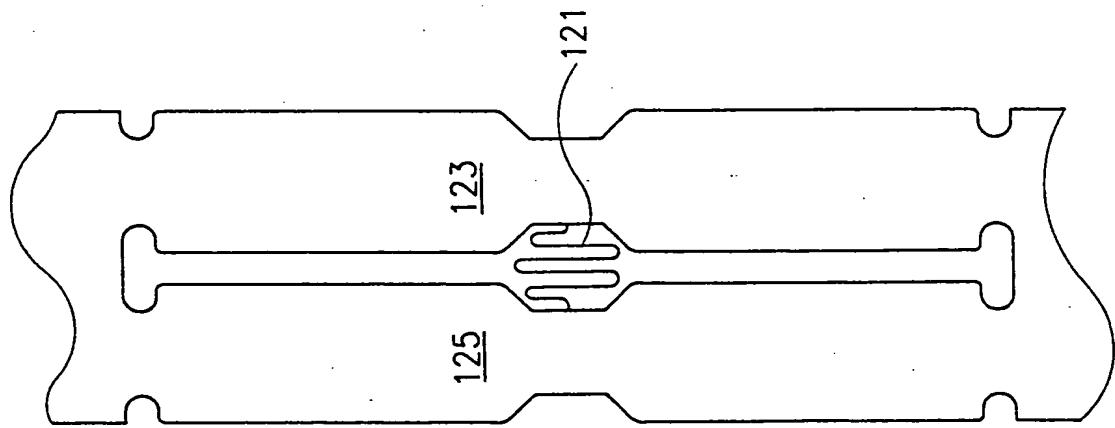
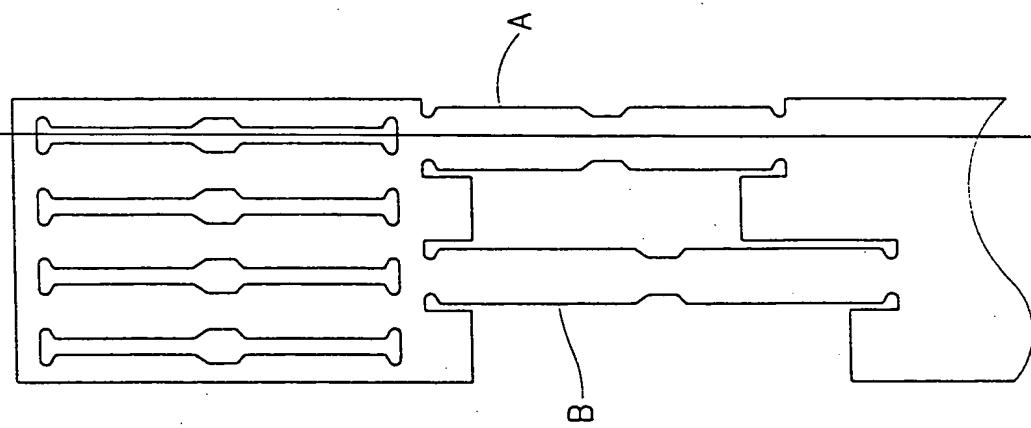
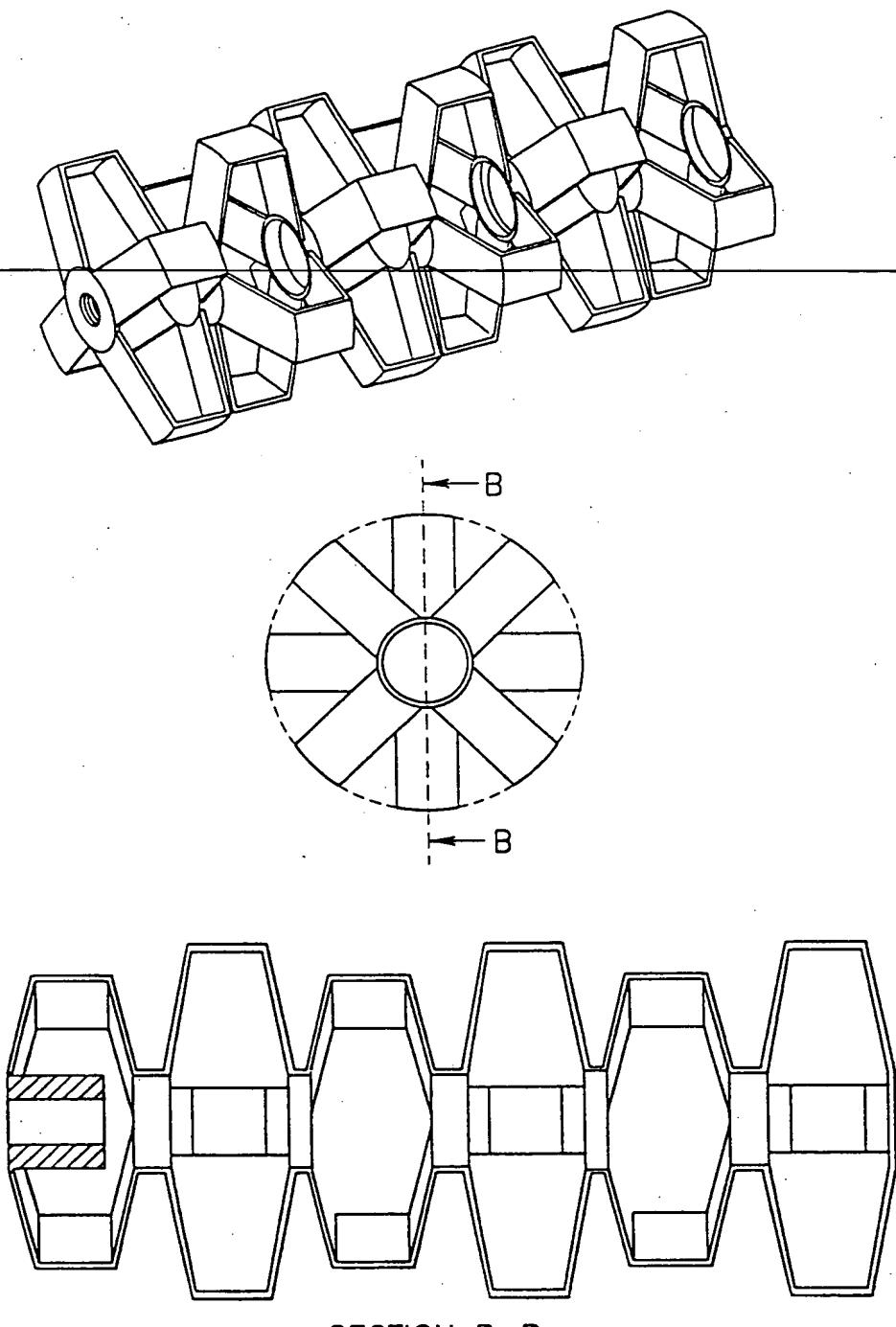


FIG.2L





SECTION B-B

FIG.20

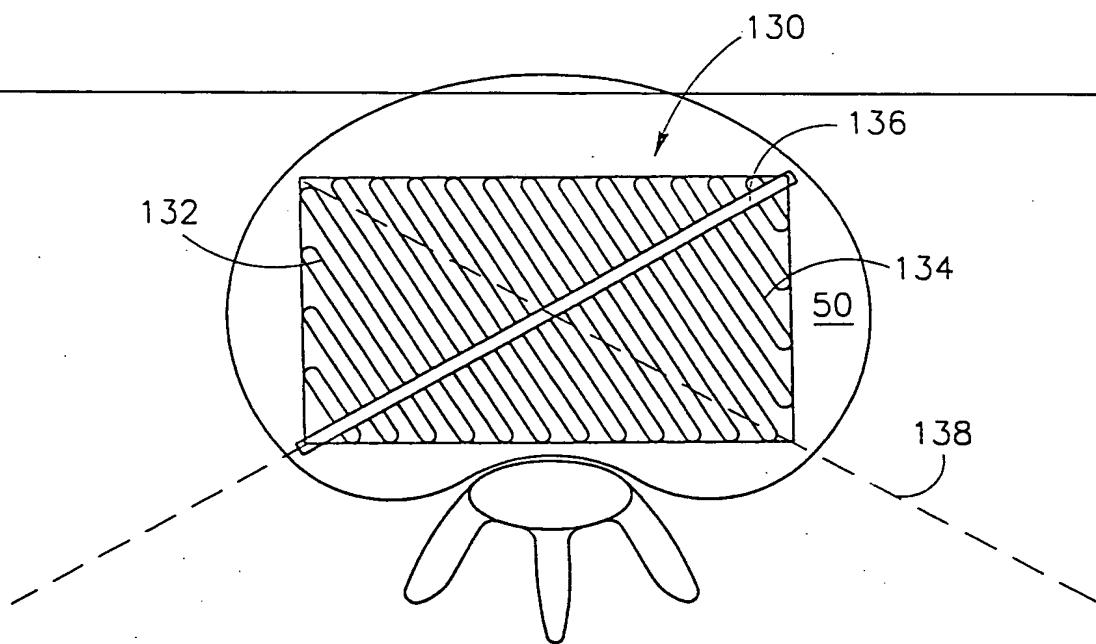


FIG.2P

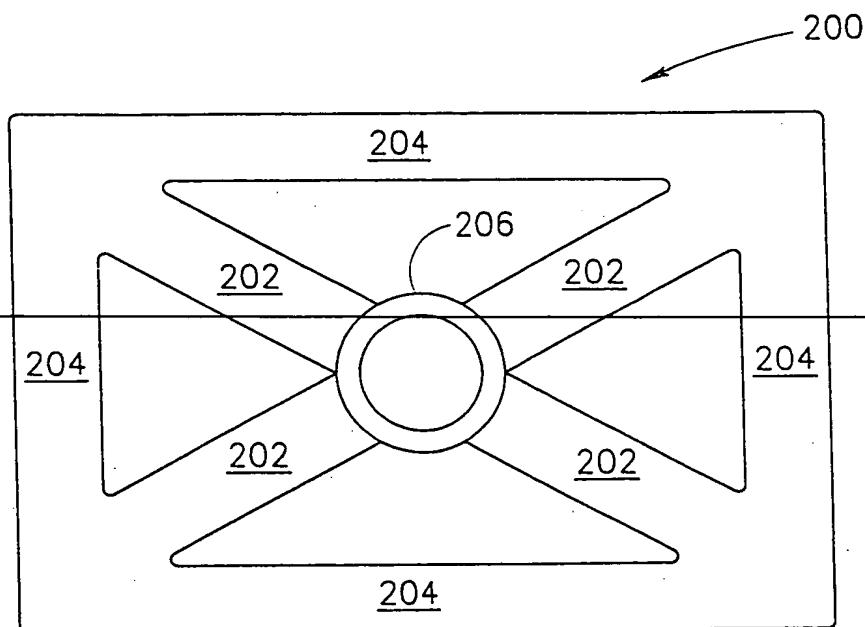


FIG.3A

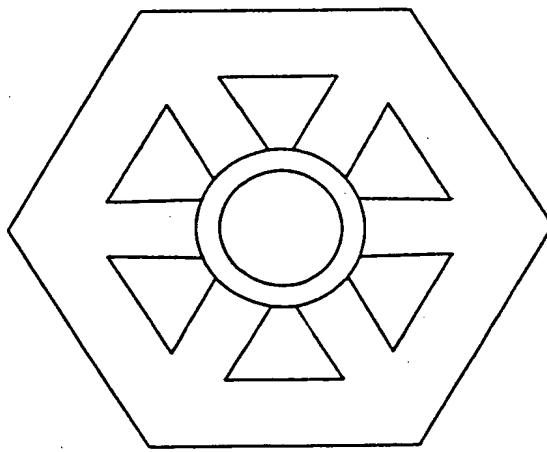


FIG.3B

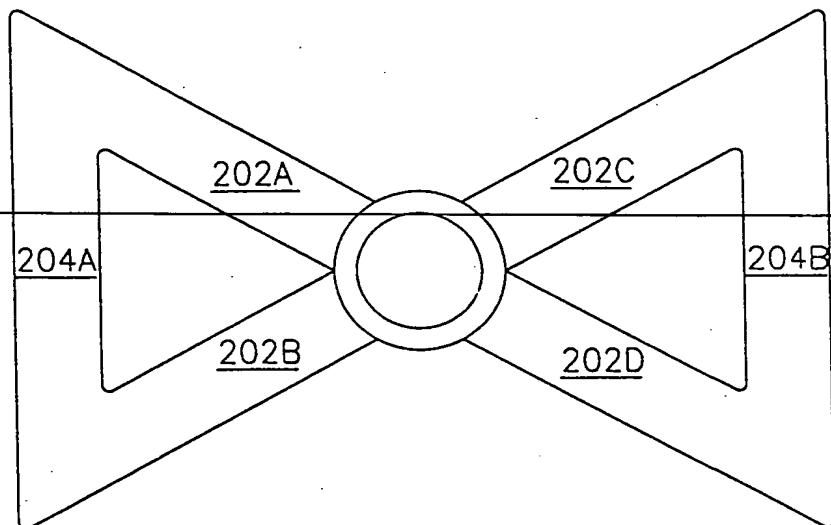


FIG.3C

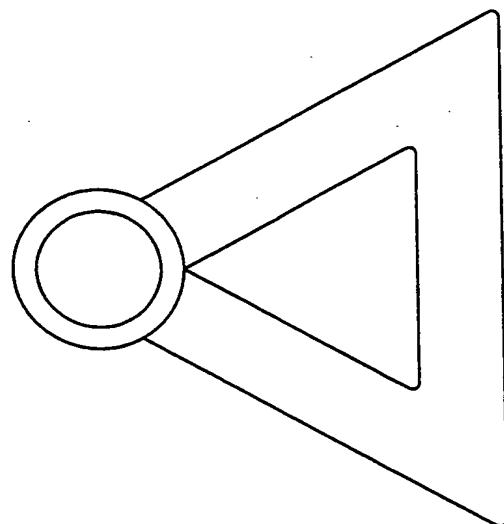


FIG.3D

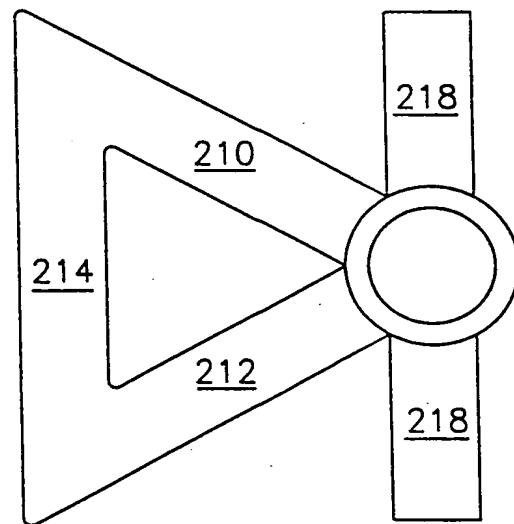


FIG.3E

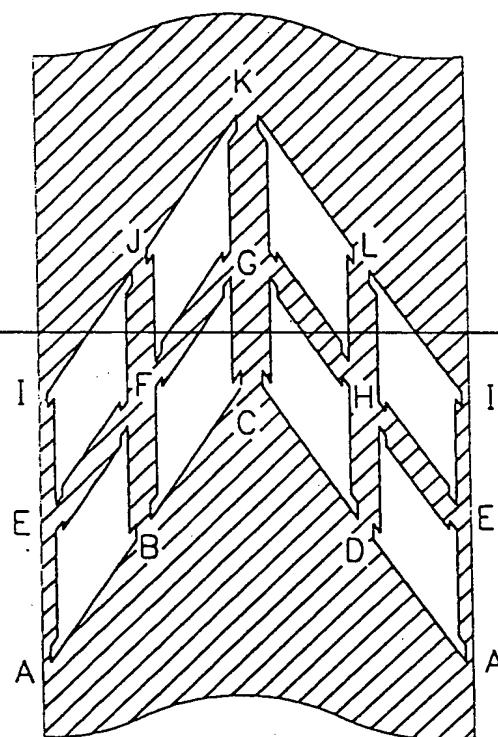


FIG. 3F

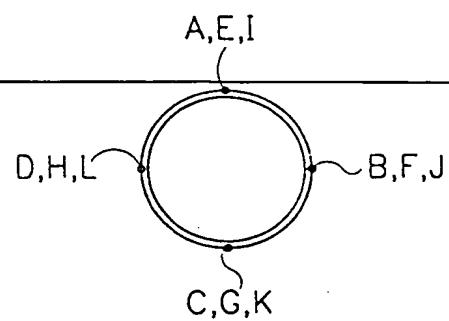


FIG. 3G

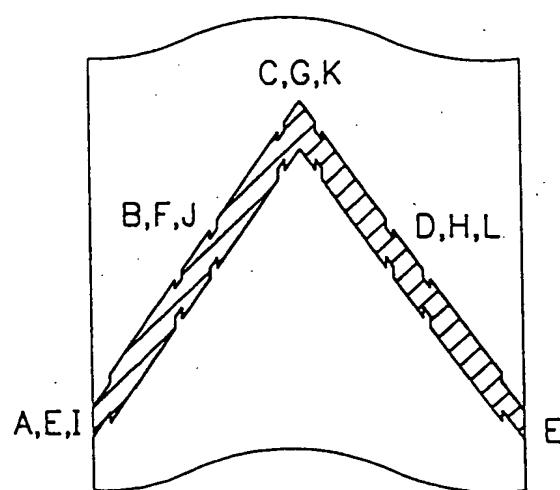


FIG. 3H

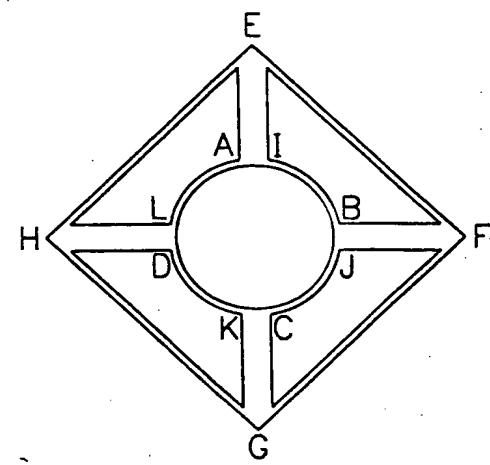


FIG. 3I

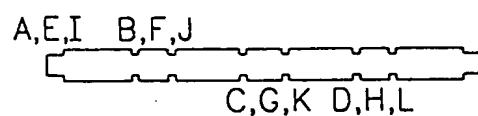
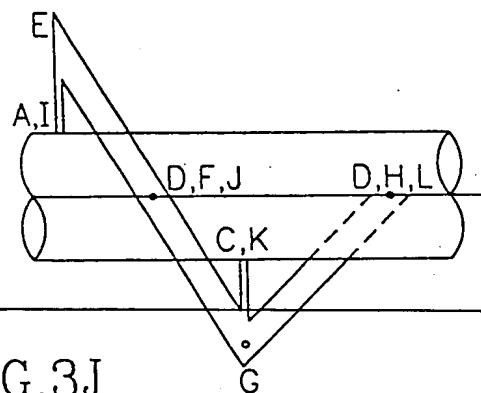


FIG.3K

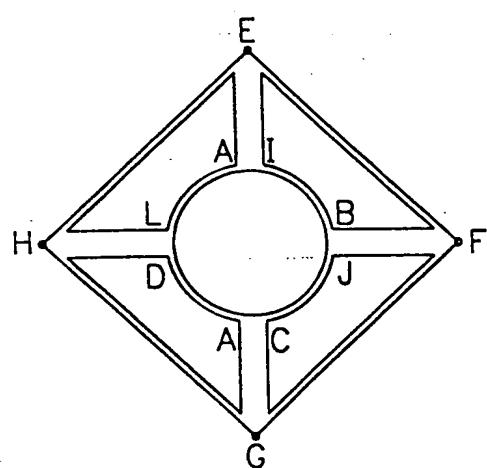


FIG.3L

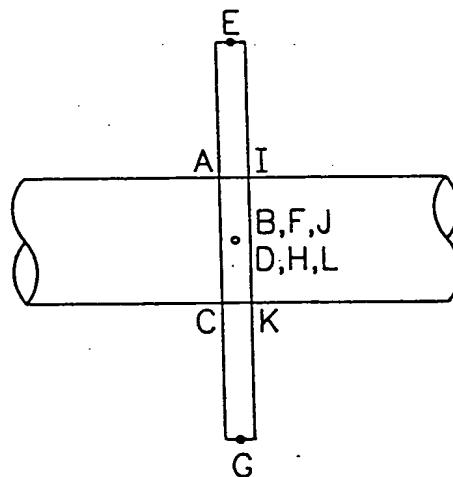


FIG.3M

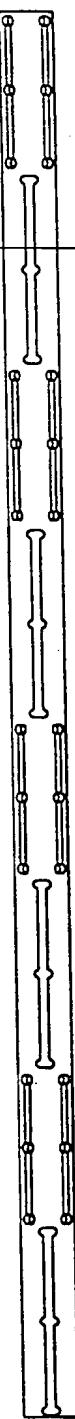


FIG. 4A

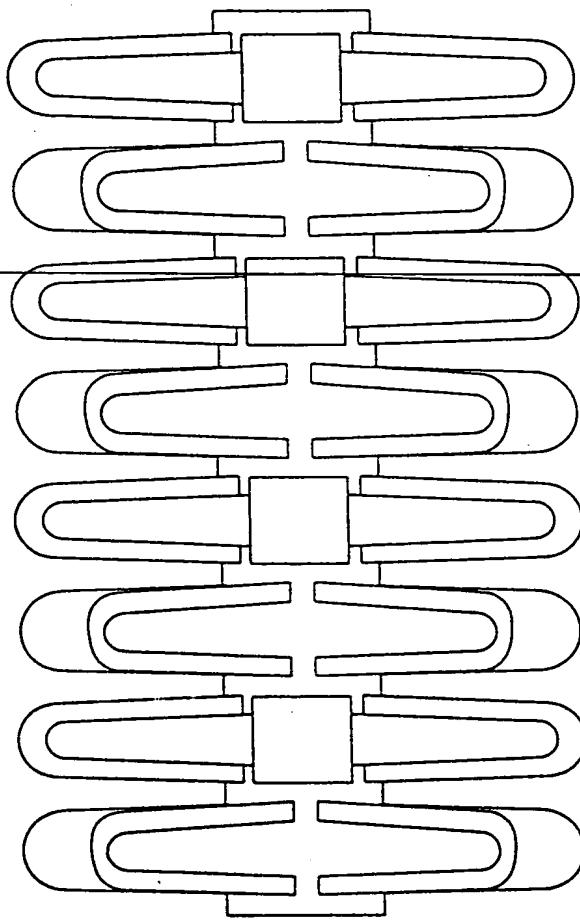
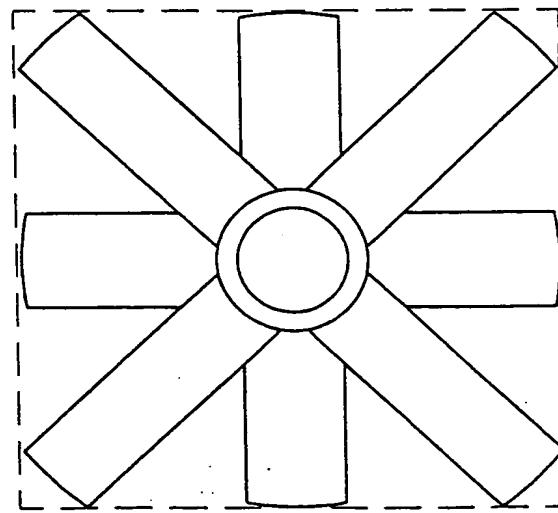


FIG.4B



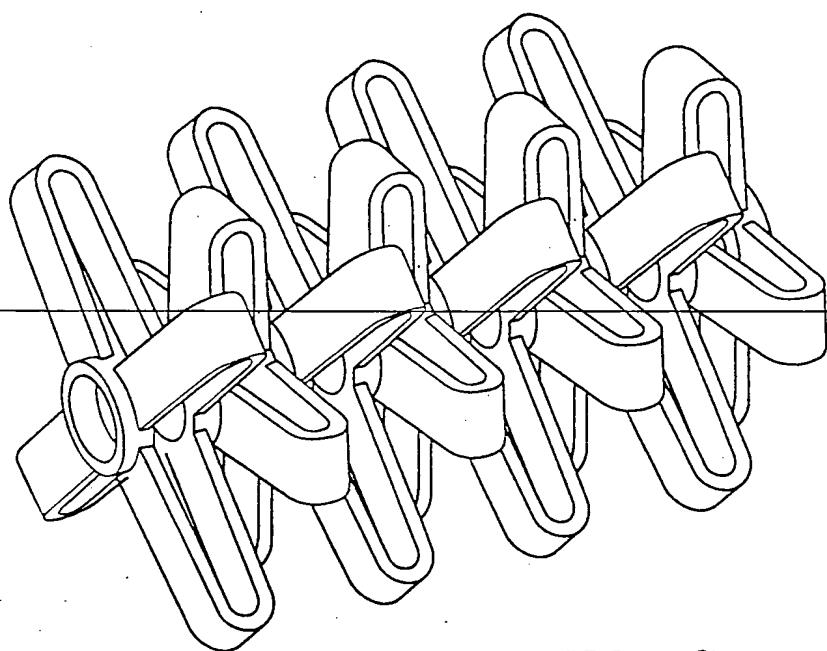


FIG.4C

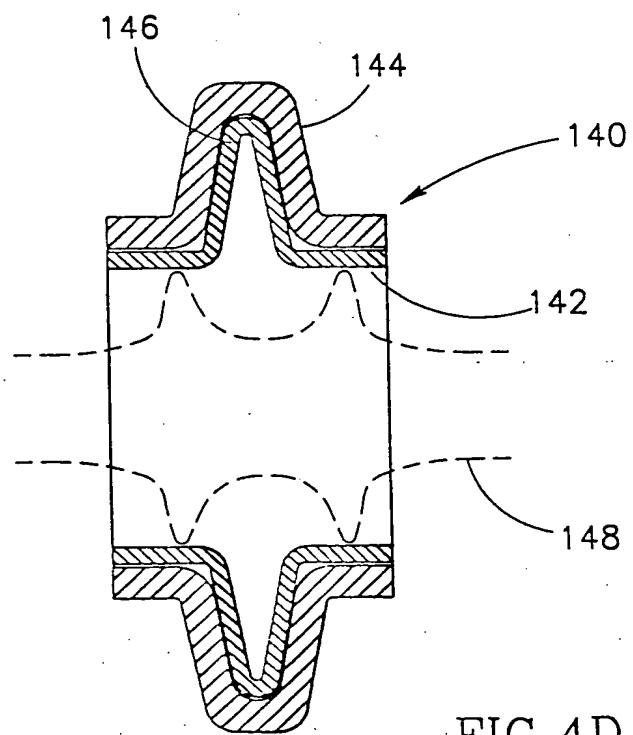
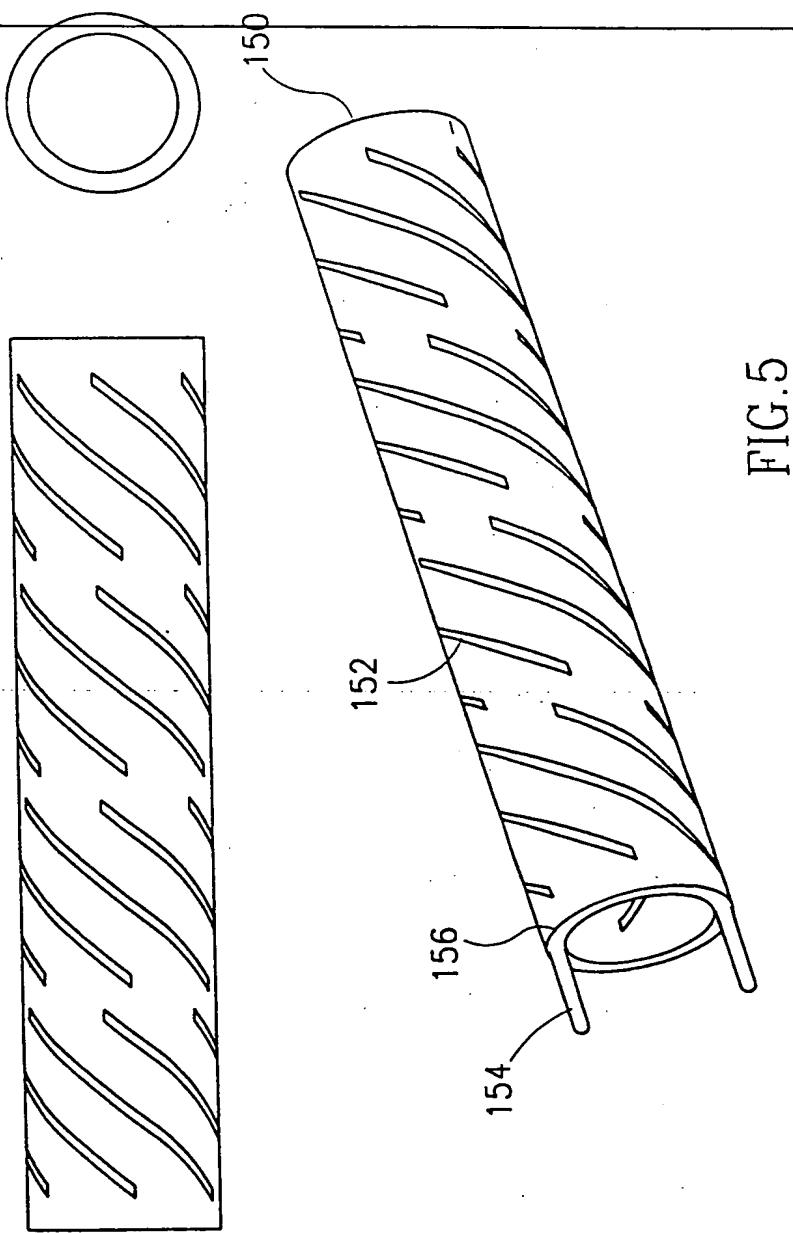


FIG.4D



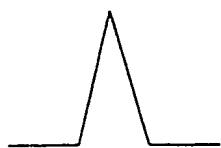


FIG.6A

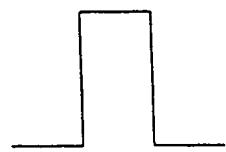


FIG.6B

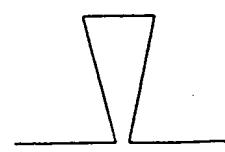


FIG.6C

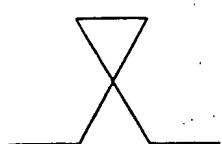


FIG.6D

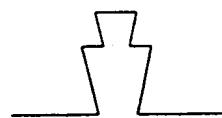


FIG.6E

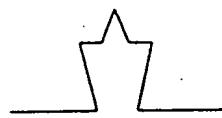


FIG.6F

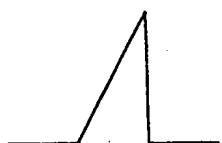


FIG.6G

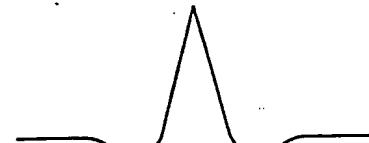


FIG.6H

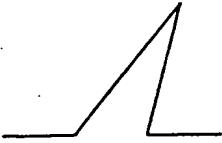


FIG.6I

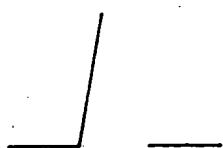


FIG.6J

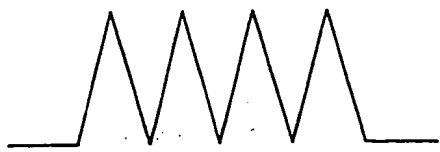


FIG.6K

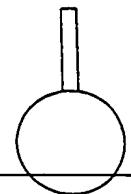


FIG.6L

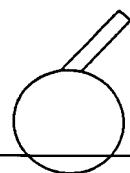


FIG.6M

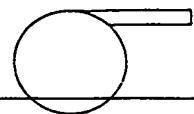


FIG.6N

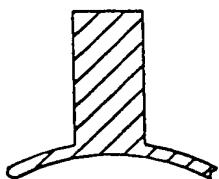


FIG.6O

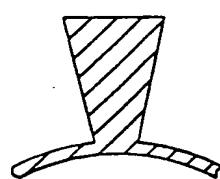


FIG.6P

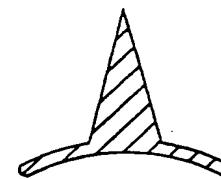


FIG.6Q

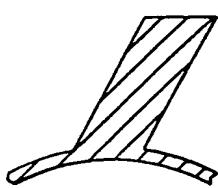


FIG.6R

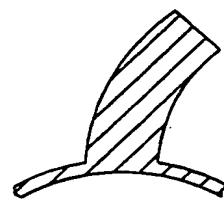


FIG.6S

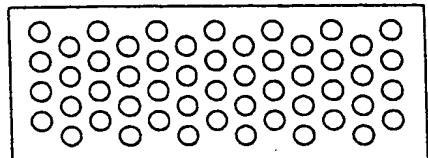


FIG. 6T

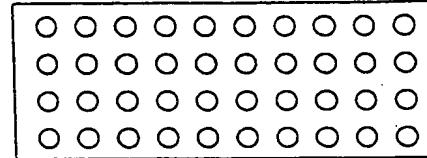


FIG. 6U

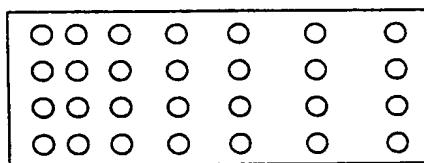


FIG. 6V

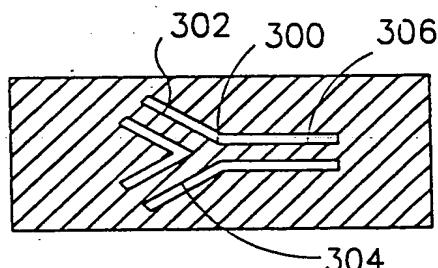


FIG. 6W

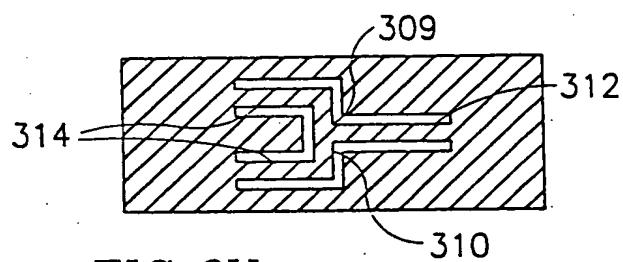


FIG. 6X

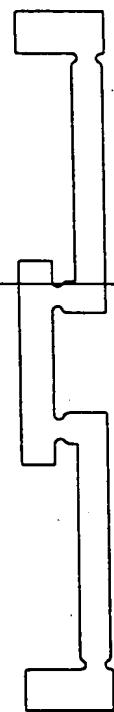


FIG. 6XA

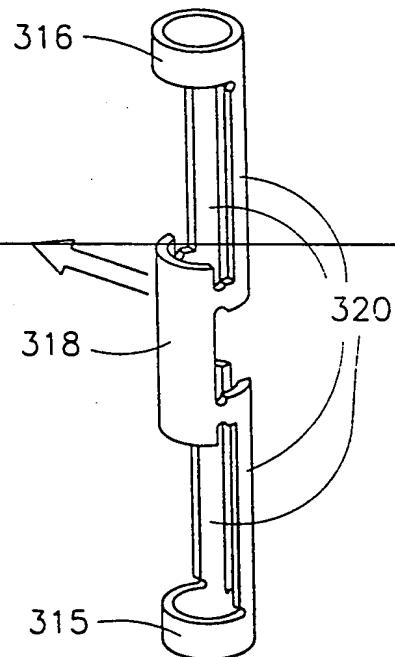


FIG. 6XB

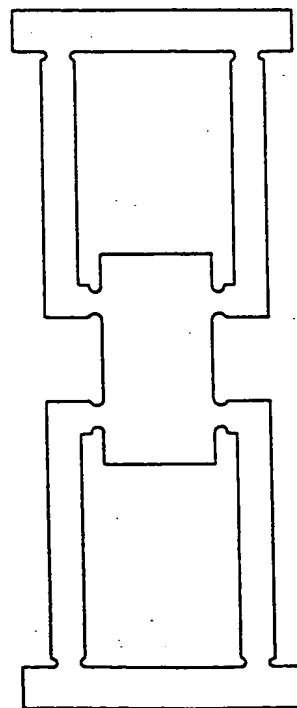


FIG. 6XC



FIG. 6XD

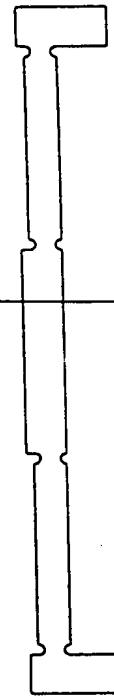


FIG. 6XE

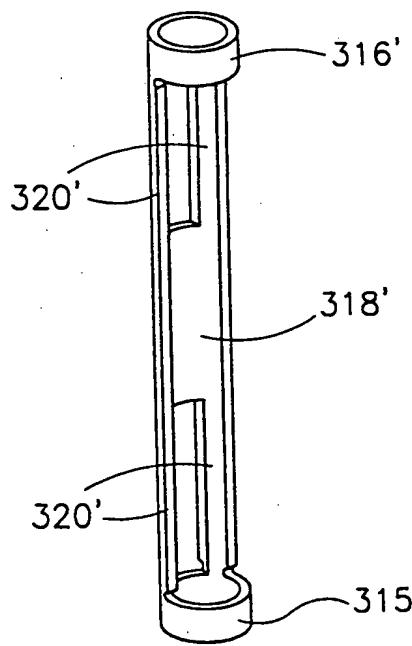


FIG. 6XF

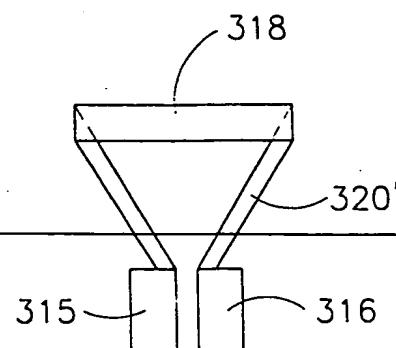


FIG. 6XG

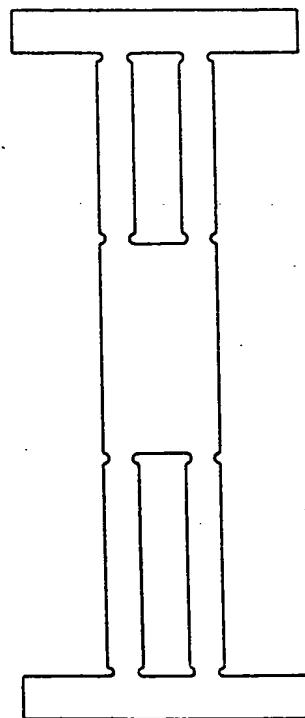


FIG. 6XH

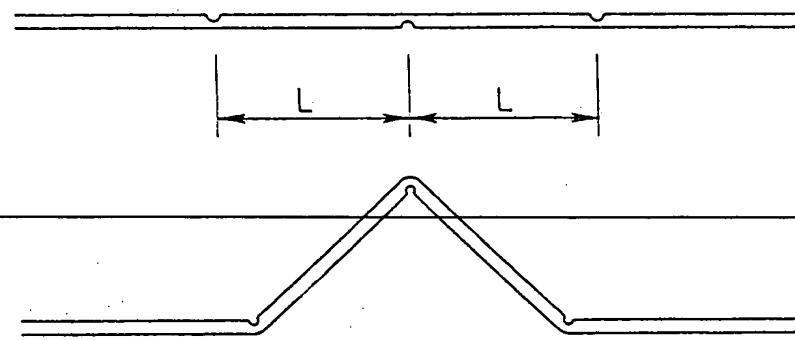


FIG.6XI

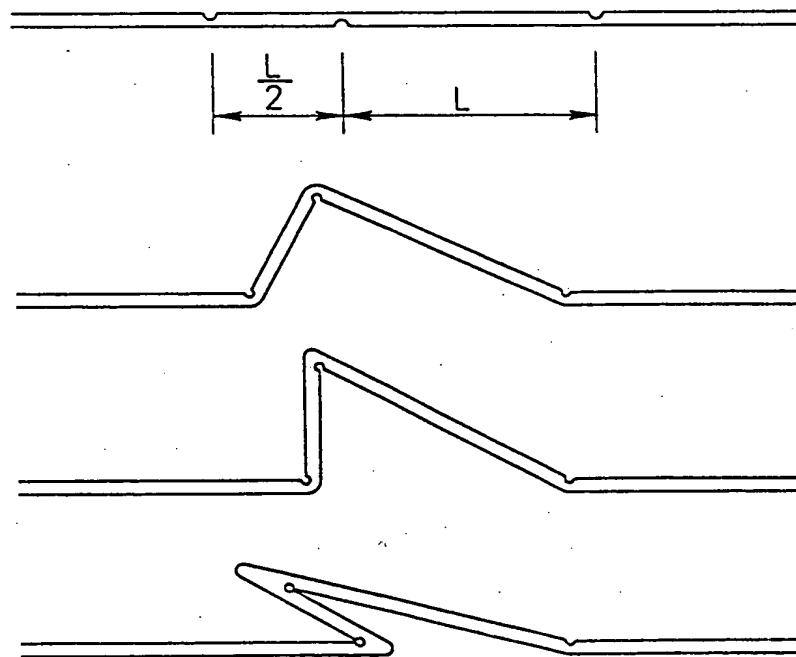


FIG.6XJ

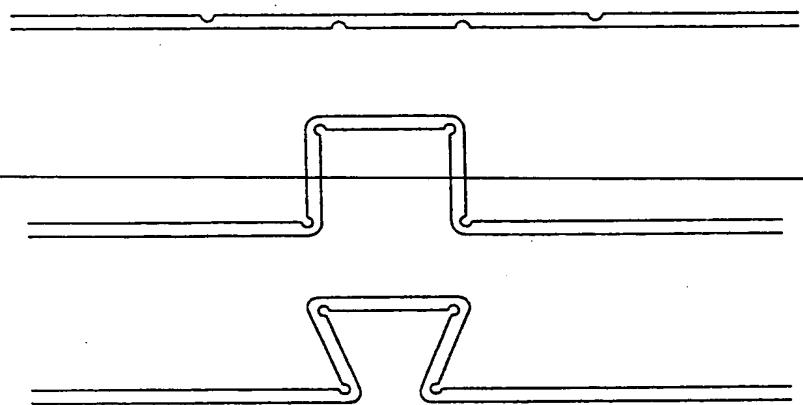


FIG.6XK

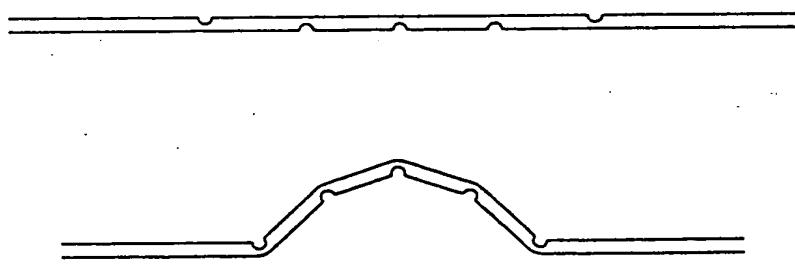


FIG.6XL

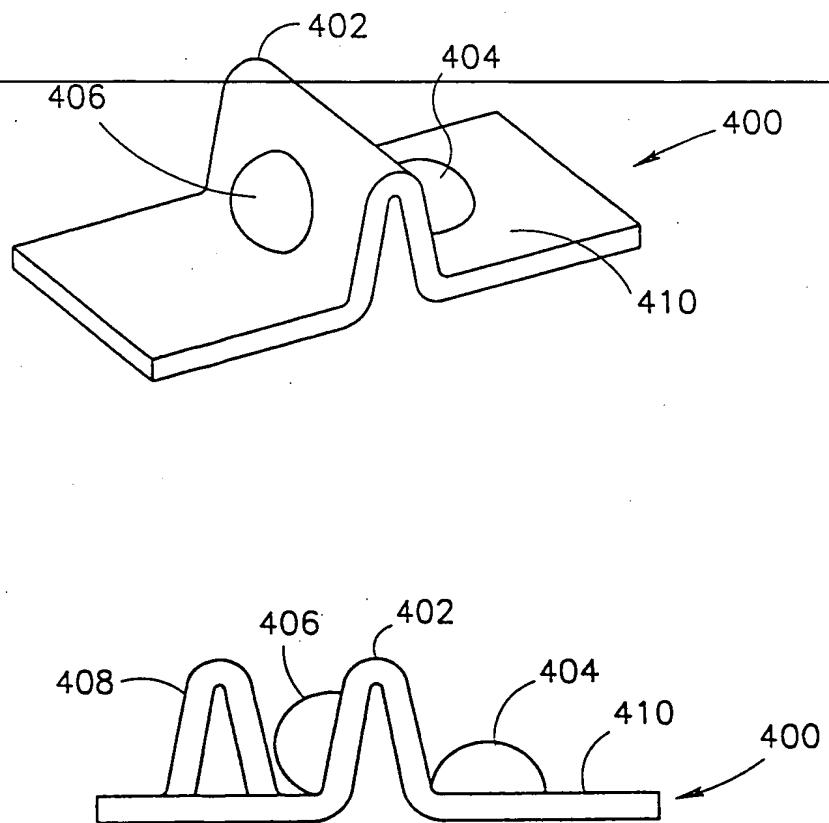


FIG. 7

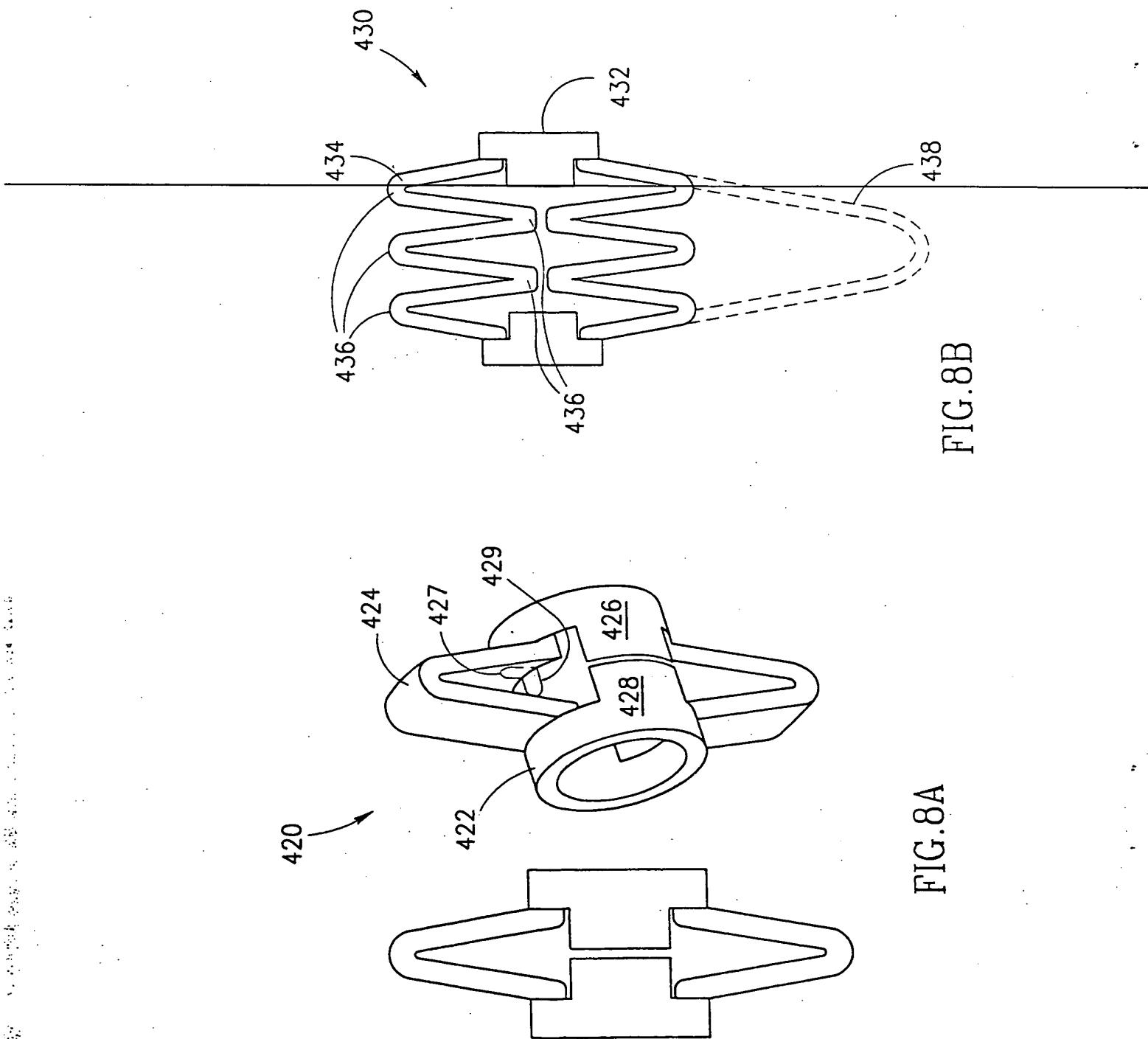


FIG. 8A
FIG. 8B

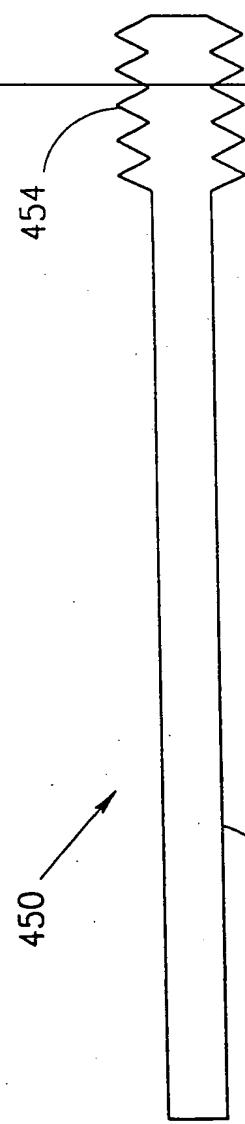


FIG. 9A

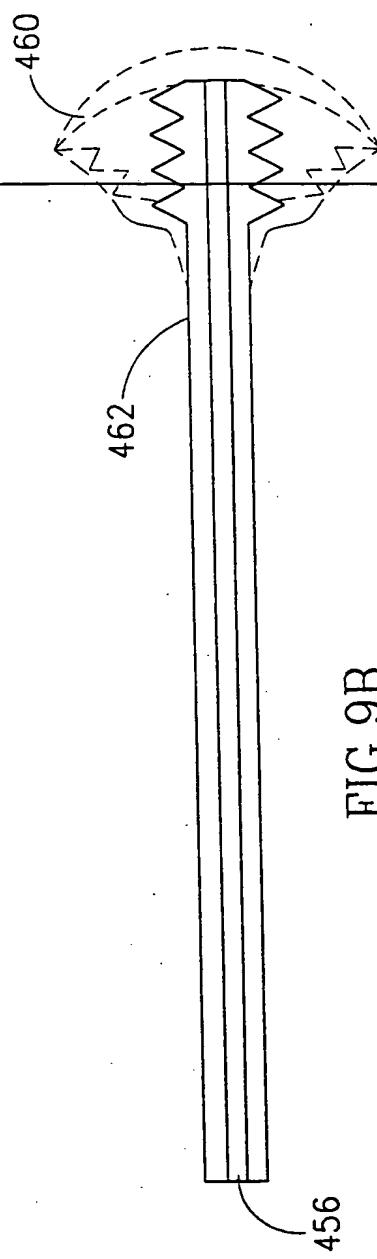
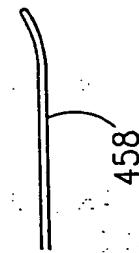


FIG. 9B



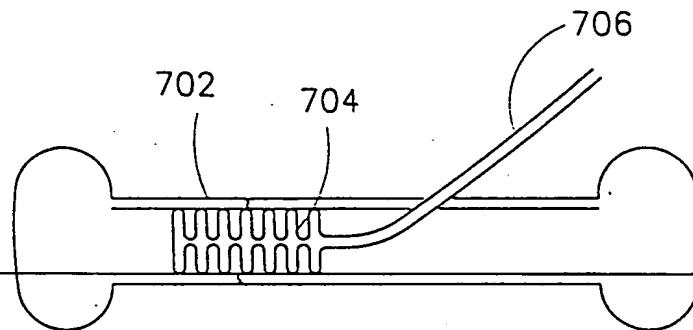


FIG.10A

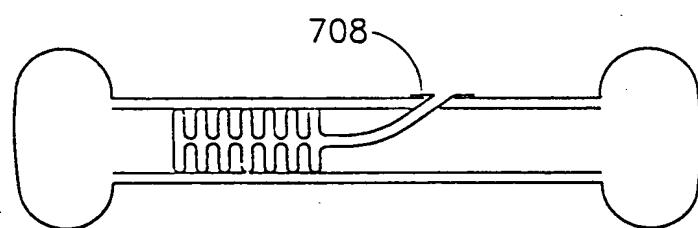


FIG.10B

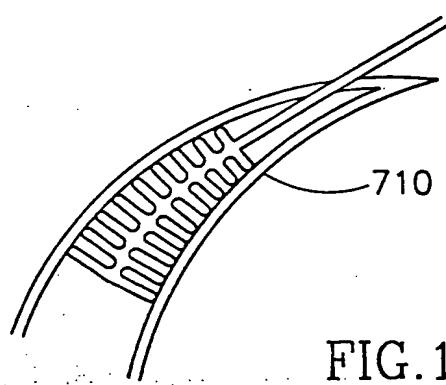


FIG.10C

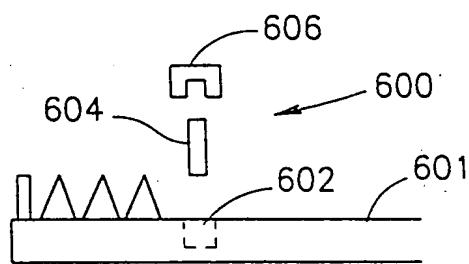


FIG. 11

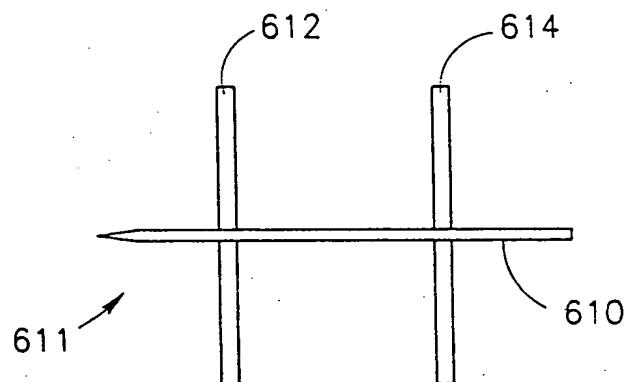


FIG. 12A

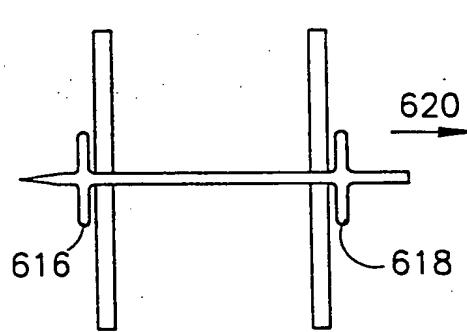


FIG. 12B

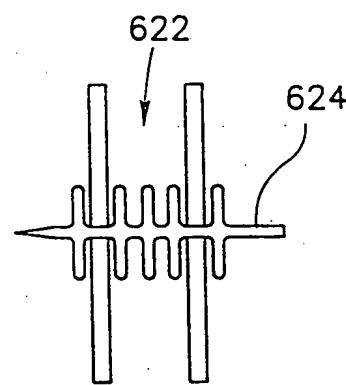


FIG. 12C

THIS PAGE BLANK (USPTO)